| 1 | Joseph J. Tabacco, Jr. (75484) | | | | | |
|----------|---|---|--|--|--|--|
| 2 | Christopher T. Heffelfinger (118058) | | | | | |
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| 7 | and Individual Class Members, Counsel for Plaintiff John Doe 2 | | | | | |
| 8 | Hollis Salzman (HS-5994) Michael W. Stocker (179083) | | | | | |
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| 12 13 | Co-Lead Class Counsel for Plaintiff Service Employees International Union Health and Welfare Fund and | | | | | |
| 14 | Institutional Class Members | iiu anu | | | | |
| 15 | UNITED STATES | S DISTRICT COURT | | | | |
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| 17 | OAKLAND DIVISION | | | | | |
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| 19 | IN RE ABBOTT LABORATORIES NORVIR ANTITRUST LITIGATION |) No. C-04-1511 CW | | | | |
| 20 | | DECLARATION OF CHRISTOPHER T.HEFFELFINGER IN SUPPORT OF | | | | |
| 21 | |) PLAINTIFFS' MOTION FOR) PRELIMINARY APPROVAL OF CLASSS | | | | |
| 22 | |) ACTION SETTLEMENT | | | | |
| 23 | |) Date: August 19, 2008) Time: 2:00 p.m. | | | | |
| 24 | |) Ctrm: 2, The Honorable Judge Wilken | | | | |
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| | | IER T. HEFFELFINGER IN SUPPORT OF NARY APPROVAL OF CLASS ACTION | | | | |

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- I, CHRISTOPHER T. HEFFELFINGER, declare as follows:
- 1. I am a member in good standing of the Bar of the State of California and of this Court. I am a member of the San Francisco office of Berman DeValerio Pease Tabacco Burt & Pucillo, co-lead class counsel and counsel for Plaintiffs John Doe 1, John Doe 2 and the Individual Class Members. The following statements are based on my personal knowledge and a review of the files in this case and, if called on to do so, I could and would testify competently thereto.
- I make this declaration in support of Plaintiffs' Motion for an Order Granting Preliminary Approval of Class Action Settlement. I discuss, in the following order: (a) background of the case; (b) a summary of the discovery that was taken in this matter before engaging in settlement discussions with Defendant; (c) a summary of the substantive motion practice that has taken place in this matter; (d) issues relating to the good-faith and arms-length negotiations between the parties; (e) the material terms of the Settlement Agreement, and (f) Class Counsels' experience and views about the proposed Settlement.
- 3. Plaintiffs sought relief from the harm which they allege Abbott caused them and the Class as a result of Abbott's leveraging its market power in the Boosted Market (Norvir) in an attempt to monopolize, or to maintain a monopoly in, the market for PIs when they are prescribed together with Norvir as a booster (the "Booster Market"). Plaintiff allege that these unlawful acts took place in the United States, beginning in December 2003 and have continued through the present day (the "Class Period"). True and correct copies of the Consolidated Amended Doe and SEIU Amended Complaints are attached hereto collectively as Exhibits A and B, respectively.

Background

- 4. The Court's Order Denying Defendant's Renewed Motion on Summary Judgment, dated July 6, 2006, provides a good background overview of the case:
 - Protease inhibitors (PIs) are considered the most potent class of drugs to combat the HIV virus. In 1996, Defendant introduced Norvir as a stand-alone PI with a daily recommended does of 1,200 milligrams (twelve 100-mg capsules a day), priced at approximately eighteen dollars per day. Norvir is the brand name for a patented
- [C-04-1511 CW] DECL OF CHRISTOPHER T. HEFFELFINGER IN SUPPORT OF PLAINTIFFS' FOR APPROVAL CLASS **ACTION** SETTLEMENT

After Norvir's release, it was discovered that, when used in small quantities with

another PI, Norvir would "boost" the anti-viral properties of that PI. Not only did a small does of Norvir, about 100 to 400 milligrams per day, make other PIs more

effective and decrease side effects associated with high doses, but it also slowed down the rate at which HIV developed resistance to the effects of PIs. The use of

Norvir as a "booster" has enabled HIV patients to live longer. But the use of Norvir as a booster, and not a stand-alone PI, has also meant that the average daily price of

Norvir has plummeted since Norvir was first introduced, because patients need only a small daily does of Norvir as a booster. By 2003, the average daily price of

In 2000, Defendant introduced Kaletra, a pill containing the protease inhibitor lopinavir and Norvir. Although effective and widely used, Kaletra had significant

In 2003, two new PIs, Bristol-Myers Squibb's Reyataz and GlaxoSmithKline's Lexiva, were about to be introduced to the market. Studies showed that, when

boosted with Norvir, the new PIs were as effective as Kaletra, and were more convenient. In July, 2003, Reyataz was successfully introduced to the market. As a

result, Kaletra's market share fell more than Defendant anticipated. The average daily does of Norvir also fell. Before Reyataz' release, the most common boosting

dose of Norvir ranged from 200 milligrams to 400 milligrams a day. Clinical trials, however, showed that a Norvir does of only 100 milligrams a day effectively

On December 3, 2003, Defendant raised by 400 percent the wholesale price of Norvir. Defendant contends that it raised Norvir's price so that it would be more in

line with the drug's enormous clinical value. Plaintiffs contend that the Norvir price increase was an illegal attempt to achieve an anti-competitive purpose in the

"boosted market," which Plaintiffs define as the market for those PIs, such as Reyataz, Lexiva and Kaletra, that are prescribed for use with Norvir as a booster.

Plaintiffs sued for violations of section 2 of the Sherman Act and California

A true and correct copy of the Court's Order Denying Summary Judgment, dated July 6, 2006, is

compound called ritonavir.

Norvir was \$1.71.

boosted Revataz.

side effects for some patients.

Business and Professions Code section 17200.

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attached hereto as Exhibit C.

Discovery and Expert Work

5. Discovery in this matter was extensive and spanned the course of about four

23 years. First, Plaintiffs propounded and reviewed a substantial amount of written discovery.

24 Collectively the Doe and SEIU plaintiffs served eight requests for production of documents, five

sets of interrogatories, and two sets of requests for admissions. Second, Plaintiffs reviewed in

excess of 500,000 pages of documents produced by Abbott and other non-parties including but

not limited to, GlaxoSmithKline and Fleishman Hilliard, as well as many volumes of

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Motion Practice

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Settlement Negotiations

parties were unable to reach an agreement at that time.

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- 26, 2006 had not been successful.
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CWI DECL OF CHRISTOPHER T. HEFFELFINGER IN SETTLEMENT

Magistrate Judge Edward A. Infante (Ret.), a well-respected mediator with the Judicial

Arbitration and Mediation Services ("JAMS"). The parties submitted detailed mediation briefs

discussing all major contested issues in the case to Judge Infante prior to the mediation. The

depositions, exhibits and testimony produced in the State Attorneys' General investigations of Norvir's price increase.

- 6. Plaintiffs also deposed over a dozen Abbott witnesses comprised of former Abbott employees, third parties, and medical and economics experts concerning the major issues in this case including market share, whether Abbott had engaged in anticompetitive conduct, and the scope and breadth of Abbott's patents, and how the market was affected by Abbott's conduct.
- 7. Plaintiffs also retained the services of two testifying experts: (1) Dr. Douglas Greer, an economist, to opine on market definition, monopoly power, Abbott's anticompetitive conduct, antitrust injury (impact), and economic injury; and (2) Dr. Paul A. Volberding, a medical doctor and a member of the faculty of the University of California San Francisco (UCSF) with extensive experience in AIDS care, research and training, to opine on, among other matters, the development and use of drug therapies to treat HIV and AIDS.

inception of this litigation. The parties fully briefed and argued, and the Court ruled on, Defendant's Fed. R. Civ. P. 12(b)(6) motion to dismiss, Defendant's three summary judgment motions, Plaintiffs' Rule 56(f) motion, Plaintiffs' Cross-Motion for Summary Judgment, and Plaintiff's Class Certification motion, as well as Defendant's motion to reconsider and for leave to file an interlocutory appeal.

Earlier settlement discussions on March 1, 2005, August 2, 2006, and September

On April 17, 2008, the parties participated in a mediation before the Honorable

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Those discussions floundered. Discussions on this topic resumed in earnest on July 28, 2008 culminating in a Memorandum of Understanding ("MOU"), executed on July 30, 2008. 12. Following execution of the MOU, the parties alerted the Court that an MOU had been executed and communicated the range of the settlement to be a low of \$10 million and a high of \$27.5 million, and, further, that the settlement was conditioned on both the Court and the

Ninth Circuit agreeing to certify a specified number of issues based on earlier orders of the

Denying in Part Abbott's Motion For Summary Judgment And Granting Plaintiffs' Motion for

Summary Adjudication of Patent Invalidity (the "5/16/08 Order"), the parties, with the assistance

of Judge Infante, renewed their settlement discussions in the context of dispensing with trial.

In mid-June 2008, following the decision by the Court Granting In Part and

Material Terms of Settlement Agreement

13. The parties then prepared a Settlement Agreement, a copy of which is attached hereto as Exhibit D. The Settlement Agreement provides that the parties will, pursuant to 28 U.S.C. § 1292(b), jointly move for certification of an interlocutory appeal on the following three issues, preceded by an interlocutory paragraph stemming from the Court's rulings on dispositive motions and related orders in this case:

In this case, Plaintiffs have alleged that Abbott's pricing decisions in December 2003 violated the Sherman Act under a monopoly-leveraging theory, and California Unfair Competition Law under Business & Professions Code §§ 17200, et seq., and further, that such conduct unjustly enriched Abbott. Plaintiffs claim that Abbott raised the price of a patented drug (Norvir) by 400% (representing a \$6.84 increase per 100mg daily dose) in one alleged market (the Booster Market) in an effort to create or maintain a monopoly for another Abbott drug known as Kaletra in a separate alleged market (the Boosted Market). Norvir's active ingredient is called "ritonavir." Kaletra is a co-formulated product that includes both ritonavir and a protease inhibitor known as "liponavir." The three proposed interlocutory issues are:

<u>Issue One</u>: Whether, as a matter of law, a plaintiff can establish antitrust injury based on the payment of an increased price for a patented product in the leveraging market, where the plaintiff contends the price increase was designed to maintain or create a monopoly in the leveraged market?

Issue Two: Whether, as a matter of law, a plaintiff can potentially establish monopoly power – in a case where the defendant allegedly used exclusionary pricing to slow a market share decline – where some existing competitors have

increased both their market share and prices since the challenged pricing decision?

<u>Issue Three</u>: Whether the Ninth Circuit's decision in *Cascade Health Solutions v. Peacehealth*, 515 F.3d 883 (9th Cir. 2008), mandates judgment against a monopoly leveraging claim based on unilateral pricing conduct where there is no allegation of below cost pricing?

- 14. The Settlement Agreement is contingent on the Court's certification of all three issues for a Section 1292 appeal, the Ninth Circuit's acceptance of at least two of these issues, and final approval by the Court.
- 15. Abbott will be entitled to final judgment, with prejudice, on all individual and class-wide claims in the case if Abbott prevails on appeal (as defined below).
- 16. For Abbott to prevail on appeal, the Ninth Circuit must accept the substance of Abbott's position on at least one of the issues accepted by the Ninth Circuit on appeal. For example:
 - 1. For Issue One, Abbott will be deemed the Prevailing Party if the Ninth Circuit holds, in substance, that Plaintiffs cannot establish antitrust injury under the law based on the price increase for Norvir;
 - 2. For Issue Two, Abbott will be deemed the Prevailing Party if the Ninth Circuit holds that under the appropriate legal standard Plaintiffs cannot establish monopoly power under the circumstances of this case;
 - 3. For Issue Three, Abbott will be deemed the Prevailing Party if the Ninth Circuit holds that a showing of below-cost pricing is necessary for the type of Sherman Act claims alleged in this case; and
 - 4. Abbott will also be deemed a Partially-Prevailing Party if, without reaching a decision falling within (1), (2) or (3), the Ninth Circuit reverses or vacates any challenged ruling or order by the Court and remands any matter or issue to the Court for reconsideration or further review based upon a legal or factual standard enunciated by the Ninth Circuit that differs from any standard applied by the Court.¹
- 17. The final decision from the Ninth Circuit, including any rehearing decision, will determine whether Abbott is the Prevailing Party. To the extent Abbott does not prevail or partially prevails based on the criteria set forth above, Plaintiffs will be deemed the Prevailing Party.

In this circumstance, Abbott will pay one-fourth of the Final Payment amount to be distributed in the same manner as detailed below.

[[]C-04-1511 CW] DECL OF CHRISTOPHER T. HEFFELFINGER IN SUPPORT OF PLAINTIFFS' MOTION FOR PRELIMINARY APPROVAL OF CLASS ACTION SETTLEMENT

18. If the Ninth Circuit accepts at least two issues for interlocutory appeal (or only one issue and Abbott declines to terminate the Settlement Agreement), Abbott will, within 10 business days of the Ninth Circuit's order, provide a non-refundable payment to the Class in the sum of \$10 million (the "Initial Payment"). The Initial Payment (net of Court-authorized deductions for attorneys' fees, costs and incentive awards) shall be distributed at the conclusion of the appellate process under the Settlement Agreement, on a *cy pres* basis, according to Exhibit C to the proposed Settlement Agreement.

- 19. If Plaintiffs are the Prevailing Party on appeal, Abbott will pay an additional \$17.5 million (the "Final Payment"), for a total of \$27.5 million. The allocation of the Initial (\$10 million) and Final Payment (\$17.5 million), net of any Court-authorized deductions for attorneys' fees, costs and incentive awards, is as follows: (1) 70% will be distributed on a *cy pres* basis; and (2) 30% will be allocated to Settlement Class Members who are consumers and Third Party Payors located in California who file valid and timely claims.
- 20. The Settlement Agreement releases any claims, demands, actions, causes of action or liability of any nature, whether known or unknown, derivative or direct, suspected or unsuspected, accrued or unaccrued, asserted or unasserted, whether in law or in equity, including, without limitation, claims which have been asserted or could have been asserted in the Action, or any litigation against Abbott arising out of the matters alleged in the Action that any Releasor (defined as any Plaintiff or Class Members) now has, ever had, could have had or may have had as of the date this Settlement Agreement is executed (whether or not such Releasor objects to settlement and whether or not he/she or it makes a claim upon or participates in the Settlement Fund, whether directly, representatively, derivatively or in any other capacity), and that all Abbott shall be forever released and discharged from any and all liability in respect of the Released Claims. Notwithstanding the above, no claims alleging damages and/or seeking nonmonetary relief cause by the failure of Norvir to be safe and/or effective or alleging other conduct not related to, or arising from, claims of the type alleged or argued in the Action, including, without limitation, claims asserted in the Direct Actions, personal injury claims,

product defect claims, securities claims, breach of contract claims, breach of warranty claims, negligence claims, tort claims, are Released Claims.

- 21. Abbott retains the right to terminate the Settlement Agreement if: (1) the Court does not grant preliminary approval of the Settlement Agreement; (2) the Ninth Circuit does not accept at least two issues for a Section 1292 interlocutory appeal; or (3) the Court or the Ninth Circuit materially modifies one or more of the three proposed issues for appeal.
- 22. The Settlement Agreement terminates automatically if the Court does not agree to certify all three issues for a Section 1292 interlocutory appeal.
- 23. If Abbott elects to terminate the Settlement, it must do so in writing within seven (7) business days of the date of the relevant court order. In that event, the appeal will be voluntarily dismissed and Abbott will have no obligation to make any payments under the Settlement Agreement. The parties will also promptly ask the Court to reset the date for trial on the next available trial date convenient to the Court, on the basis of the pretrial proceedings that have already occurred.

Class Counsels' Views

- 24. As part of its Class Certification Order, the Court appointed the law firms of Berman DeValerio Pease Tabacco Burt & Pucillo ("Berman DeValerio") as counsel for the Class for the subclass of individual members; and the appointed the law firm of Labaton Sucharow & Rudoff, LLP (currently, Labaton Sucharow, LLP) ("Labaton") as counsel for the Class and for the subclass of the institutional class members.
- 25. The Berman firm has extensive experience in prosecuting and resolving antitrust and class action cases. I am aware of the reputation of the Labaton firm and understand that this firm similarly has significant antitrust and class action experience.
- 26. In my view and the collective view of Class Counsel, the settlement is fair, reasonable and adequate, when taking into consideration the strengths and weaknesses of the claims and defenses, the evidence, and the continued risks of litigation.
 - 27. As described above, the Settlement consists of a low/high of \$10 million or \$27.5

million depending on the ultimate disposition of the appellate issues identified above. If simply the low-end of \$10 million is achieved, then these funds after payment of court-authorized fees and costs will be distributed on a *cy pres* basis according to Schedule C of the proposed Settlement Agreement. If, however, the high end of \$27.5 million is achieved, then following the payment of court-authorized fees, costs, and incentive awards to the named Class Representatives, the funds shall be allocated as follows: (1) 70% will be distributed on a *cy pres* basis; and (2) 30% will be allocated to Settlement Class Members who are consumers and TPPs located in California who file valid and timely claims.

Class Representatives' Views

- 28. In connection with the settlement negotiations, Class Counsel acted in the best interests of the class as a whole.
- 29. I have discussed the Settlement with both Doe 1 and Allen Thornell. I am informed and believe that counsel for SEIU similarly discussed the Settlement and its terms with representatives of the SEIU. The Class Representatives supported Class Counsel's recommendation to enter into the Settlement Agreement.
- 30. Consistent with the Settlement Agreement, Class Counsel will make a request to the Court for an award of incentive payments to the Class Representatives in an amount to be determined by the Court.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

Christopher T. Heffelfinger

Executed at San Francisco, California, on August 13, 2008.

EXHIBIT A

| | 7 (75404) | | | | | | |
|----------|--|--------------------------------------|--|--|--|--|--|
| 2 | Joseph J. Tabacco, Jr. (75484) Sharon T. Maier (144910) Michael W. Stocker (179083) | | | | | | |
| 3 | BERMAN DeVALERIO PEASE TABACCO BURT & PUCILLO | | | | | | |
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| 5 | Telephone: (415) 433-3200 Facsimile: (415) 433-6382 | | | | | | |
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| 7 | | | | | | | |
| 8 | UNITED STATES DISTRICT COURT | | | | | | |
| 9 | FOR NORTHERN DISTRICT OF CALIFORNIA | | | | | | |
| 10 | | 1 | | | | | |
| 11 | JOHN DOE 1 and JOHN DOE 2, on Behalf of Themselves and All Other Persons Similarly Situated, | Case No. | | | | | |
| 12 | Plaintiffs, | FIRST AMENDED CLASS ACTION COMPLAINT | | | | | |
| 13 | v. | } | | | | | |
| 14 | ABBOTT LABORATORIES, | Ś | | | | | |
| 15 | Defendant. |)) <u>JURY TRIAL DEMANDED</u> | | | | | |
| 16 | | } | | | | | |
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| 19 | INTRODUCTION | <u> </u> | | | | | |
| 20 21 | 1 Distriction Teles Dec 1 and John Dec 0 and 1 d 10 Cd and the Dec 1 | | | | | | |
| 22 | 1. Plaintiffs John Doe 1 and John Doe 2, on behalf of themselves and all others | | | | | | |
| 23 | similarly situated, bring this action against Abbott Laboratories ("Abbott," "Defendant," or the "Company") for injunctive relief under the antitrust laws of the United States and for such other | | | | | | |
| 24 | relief as appropriate under California Business and Professions Code Section 17200, et seq, and | | | | | | |
| 25 | common law. | | | | | | |
| 26 | JURISDICTION AND VENUE | | | | | | |
| 27 | 2. This Court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1337 | | | | | | |
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| | FIRST AMENDNED CLASS ACTION COMPLAINT | | | | | | |
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over the state law and common law claims pursuant to 28 U.S.C. § 1367.

3. Defendant transacts business, maintains offices, or is found within the state of California. The interstate commerce described in this First Amended Complaint is carried on, in part, within this District. Venue is proper in this District pursuant to the provisions of 15 U.S.C. §§ 22 and 28 U.S.C. § 1391.

PLAINTIFFS

- 4. Plaintiff John Doe 1 is a citizen of the state of California, residing in the City and County of San Francisco. John Doe 1 has sued using a pseudonym to protect his privacy. John Doe 1 purchased Norvir for use as a booster to a protease inhibitor after December 3, 2003 and was thus injured as a result of Abbott's alleged violations.
- Plaintiff John Doe 2 is a citizen of the state of Georgia, residing in Cobb County. John Doe 2 has sued using a pseudonym to protect his privacy. John Doe 2 purchased Norvir for use as a booster to a protease inhibitor after December 3, 2003 and was thus injured as a result of Abbott's alleged violations.

DEFENDANT

6. Abbott is a corporation organized, existing, and doing business under the laws of the state of Illinois. Its office and principal place of business is located at 100 Abbott Park Road, Abbott Park, Illinois 60064. Abbott is engaged principally in the development, manufacture, and sale of pharmaceuticals and health care products and services. Abbott had sales of \$19.3 billion in 2003, of which \$4.3 billion was attributable to its anti-viral pharmaceuticals. Abbott operates in 130 countries and has facilities in 14 states, including at least 3 in this District.

TRADE AND COMMERCE

- 7. During the Class Period defined below, Abbott marketed and sold its HIV drug Norvir in a continuous stream of commerce to customers located in states other than Illinois, where it resides. Abbott also marketed and sold its HIV drug Kaletra in a continuous stream of commerce to customers located in states other than Illinois, where it resides.
- Abbott's business activities that are the subject of this First Amended Complaint were in the flow of, and substantially affected, interstate trade and commerce. Abbott frequently

Invirase (saquinavir), manufactured by Roche Laboratories, approved by the Crixivan (indinavir), manufactured by Merck, approved March 1996; Norvir (ritonavir), manufactured by Abbott, approved March 1996; Viracept (nelfinavir), manufactured by Agouron Pharmaceuticals, approved manufactured Roche Agenerase (amprenavir), manufactured by GlaxoSmithKline, approved Kaletra (the PI lopinavir boosted by ritonavir), manufactured by Abbott, Reyataz (atazanavir), manufactured by Bristol-Myers Squibb, approved Lexiva (fosamprenavir), manufactured by GlaxoSmithKline, approved Each of these PIs, like any anti-HIV drug, will eventually lose efficacy as the virus FIRST AMENDNED CLASS ACTION COMPLAINT

develops resistance to it. When such resistance occurs, the failed PI must be replaced with another PI that is able to overcome the virus' resistance. Because successive PI regimens must be used in a sequence carefully calibrated to reflect the virus' evolving mutations in individual patients, preserving a maximum number of PI treatment options for physicians to choose from is of paramount importance to the survival of people with HIV.

- 13. Norvir is a drug patented, produced, distributed, and sold by Abbott. Abbott developed Norvir with the assistance of a National Institutes of Health grant and spent only about \$15 million of its own funds on pre-approval clinical trials for the drug. Abbott is the sole maker of Norvir, and there are no generics or functionally equivalent formulations on the market. By the end of 2001, Norvir had generated cumulative sales for Abbott of more than \$1 billion (more than sixty times the estimated cost of its pre-approval outlays). Securities analysts have estimated that, even without the price increase that is the subject of this First Amended Complaint, Norvir would generate more than \$2 billion for Abbott over the next ten years.
- 14. Norvir was originally developed as a PI and was approved for use as a stand-alone drug or for use in combination with other PIs in March 1996. Serious side effects prevented Norvir from ever being successfully marketed as a PI. However, small doses of the drug were found to dramatically improve blood levels of other PIs, decreasing the side effects associated with those drugs and "boosting" the antiviral effect of PIs against even resistant strains of HIV. For such boosting purposes, there is no substitute for Norvir. The "Booster Market" thus consists of the market for Norvir, while the "Boosted Market" consists of the market for PIs only when they are prescribed together with Norvir as a booster. Other advantages of Norvir-boosted PI regimens over regimens without Norvir include convenience in terms of pill burden and reduction of food restrictions for patients, both important factors in ensuring adherence to antiretroviral therapy.
- 15. Perhaps even more importantly, recent research has shown significant benefit for the use of boosted PI regimens, especially for patients who experience failure of treatment

 regimens combining PIs with other anti-HIV drugs. Such treatment failures are marked by the emergence of drug-resistant mutations that limit the benefit of other drugs in the future, because of cross-resistance between HIV medications. When patients experience failure of initial boosted PI regimens, there is no evidence of PI resistance and, moreover, there is less resistance to the other drugs in the regimen. Hence, by using Norvir to boost PI regimens, physicians can maximize the treatment options remaining for the patients experiencing treatment failure.

- 16. In addition to Norvir, Abbott also markets its own Norvir-boosted PI, Kaletra. Kaletra consists of Abbott's PI lopinavir, combined in pill form with Norvir as a boosting agent. Kaletra has significant side effects, however, most notably hyperlipidemia, rendering patients significantly more vulnerable to heart attacks and strokes.
- 17. Prescriptions for Kaletra had steadily risen since its September 2000 introduction, and by June 2003, new prescriptions and total sales of the drug had reached an all-time high, securing Kaletra an approximate 75% share of the Boosted Market. However, Kaletra's domination of the Boosted Market was about to be seriously threatened.
- 18. With the June 2003 introduction of Bristol-Myers Squib's competing PI, Reyataz, a new PI boosted by Norvir, Kaletra's share of new PI prescriptions began a precipitous decline. By October 2003, the press reported that Kaletra had "topped out." Furthermore, Kaletra prescriptions, as a proportion of the Boosted Market, began to plummet in the two months following the introduction of Reyataz. To make matters worse, October 2003 saw GlaxoSmithKline introduction of Lexiva, another PI boosted by Norvir. Both Reyataz and Lexiva began to make made steady inroads against Kaletra's boosted PI market share.
- 19. Abbott acted quickly to stanch these losses and maintain its dominant position in the Boosted Market. On December 3, 2003, barely five weeks after the release of GlaxoSmithKline's Lexiva and more than seven years after Norvir's introduction into the market, Abbott abruptly announced that it was raising the wholesale price of Norvir from \$205.74 to \$1,028.71 for 120 100 mg capsules an increase of approximately 478%.
- 20. By means of this staggering price hike, Abbott added drastically to the cost of regimens using Norvir to boost competing PIs. The annual cost of the Norvir needed to boost

 these drugs increased by \$6,258 per year for PIs such as Lexiva requiring twice-daily doses of Norvir. For Tipranovir, a PI currently in development by Boehringer-Ingleheim, the optimal Norvir booster dose would increase by more than \$12,000 per year.

- 21. In a *coup de grace* against competitors' PIs, Abbott did not raise the price of the Norvir used in its own Kaletra. As a result, Kaletra became the least expensive boosted regimen in the Boosted Market. By leveraging its power in the Booster Market, Abbott unlawfully maintained or extended its monopoly in the Boosted Market.
- 22. Abbott's actions also had a chilling effect on the research efforts of competitors such as Boehringer-Ingleheim that seeks to develop future generations of PIs and is heavily reliant on Norvir's boosting properties. As one pharmaceutical company research scientist recently stated in the press, "[w]hy bother investing in these areas if Abbott has effectively priced you out of the market in the US?" The same scientist suggests that, by pricing others out of the market, Abbott will effectively shape the research evidence base in such a way as to ensure that all roads lead to its products.
- 23. Abbott's monopolistic intentions were immediately apparent to an outraged public. The Attorneys General of Illinois and New York launched investigations into the price increase. The Illinois Attorney General stated in a February 6, 2004 press release:

Critics of this price jump by the suburban Chicago-based drug giant say the increase is aimed at undercutting competitors' products and helping Abbott gain a larger market share for its new combination of all-Abbott drugs to suppress HIV. In the past, Abbott's Norvir has been combined with other drug companies' products in HIV suppression "cocktail" combinations.

- 24. Physicians prescribing PIs overwhelmingly agree with the fears expressed in the Illinois Attorney General's statement. The Organization of HIV Healthcare Providers, representing physicians collectively treating approximately 85,000 patients with HIV, stated in a January 20, 2004 letter to Abbott that in hiking Norvir's price Abbott was "taking advantage of a monopolistic situation, where [its] product is the only effective protease inhibitor boosting agent."
- 25. The effects of Abbott's anticompetitive activities are already being felt by an extraordinarily vulnerable population. At least one hospital that has already revised its formulary —

the list of preferred drugs that physicians may use — because of cost, to give preference to Kaletra and restrict physicians' options to use other drugs.

RELEVANT MARKETS

- 26. All but one of the protease inhibitors currently prescribed for the treatment of HIV benefit from the use of Norvir as a "booster" in order to maximize the blood levels of the drug and minimize toxic side effects. Indeed, many public health assistance programs *require* the use of Norvir as the booster for a PI regimen. Abbott has virtually a 100% share of the multimillion-dollar Booster Market in the United States
- 27. The Boosted Market consists of the market for PIs only when prescribed together with Norvir as a booster. Many of the PIs currently in use and all PIs in clinical trials are used and prescribed together with Norvir as a booster. Abbott's Norvir-boosted PI product, Kaletra, is sold in this Boosted Market.
 - 28. The United States is the geographical market.

CLASS ACTION ALLEGATIONS

29. Plaintiffs bring this action on their own behalf and as a class action under the provisions of Rule 23(a), (b)(2), and (b)(3) of the Federal Rules of Civil Procedure on behalf of the following class:

All persons or entities (excluding Abbott, its parents, subsidiaries, and affiliates, and governmental entities) who purchased Norvir indirectly as a booster to other PIs and who paid all or part of the increased cost of Norvir, from December 3, 2003 to the present (the "Class Period").

- 30. Plaintiffs do not know the exact number of class members. Due to the nature of the trade and commerce involved, however, Plaintiffs believe that the class members are sufficiently numerous and geographically dispersed throughout the United States that joinder of all class members is impracticable.
- 31. Except as to the amount of individual damages each class member has sustained, all relevant questions of fact and law are common to the class, including, but not limited to, the following:
 - a. Whether Abbott unlawfully attempted to monopolize the Boosted Market

The questions of law and fact common to class members predominate over any

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questions affecting only individual members, including legal and factual issues relating to liability and damages.

35. A class action is superior to other methods available for the fair and efficient adjudication of this controversy. Treatment as a class action will permit a large number of similarly situated persons or entities to adjudicate their common claims in a single forum simultaneously, efficiently, and without the duplication of effort and expense that numerous individual actions would engender. Class treatment will also permit the adjudication of claims by many class members who could not afford individually to litigate an antitrust claim such as is asserted in this First Amended Complaint. This action likely presents no difficulties in management that would preclude its maintenance as a class action. Finally, the class is readily ascertainable.

FIRST CAUSE OF ACTION Sherman Act § 2 (15 U.S.C. § 2)

- 36. Plaintiffs incorporate allegations set forth above, as if fully stated here.
- 37. At all relevant times, Abbott possessed a monopoly in the Booster Market.
- 38. The Booster Market and the Boosted Market constitute separate, relevant product markets.
- 39. Abbott possessed and acted with specific intent to achieve an anticompetitive purpose, including the intent to eliminate competitors from the Boosted Market and to unlawfully maintain its monopoly in the Boosted Market.
- 40. Abbott engaged in one or more of the predatory or anticompetitive acts alleged in this First Amended Complaint
- 41. There is a dangerous probability that Abbott will be successful in achieving or in unlawfully maintaining a monopoly in the Boosted Market.
 - 42. There is no pro-competitive justification for Abbott's actions.
 - 43 Abbott acted with an anticompetitive purpose resulting in an anticompetitive effect.
 - Abbott's acts and conduct were committed for the following purposes:
 - a. to eliminate competitors from the Boosted Market;

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- b. to chill the development of potentially competing PIs that require a booster such as Norvir; and
- c. to unlawfully maintain a monopoly in, or attempt to monopolize, the Boosted Market.
- 45. These acts by Abbott have restrained or prevented competition and threaten and continue to restrain and prevent competition.
- 46. Plaintiffs and class members have been injured in their business or property by reason of Abbott's antitrust violations. Their injury consists of being forced to pay higher prices for Norvir, which is an essential element of their HIV treatment, than would otherwise occur in a fair and competitive market. Those injuries are of the type the antitrust laws were designed to prevent and flow from that which makes Abbott's conduct unlawful.
- 47. As a consequence, Plaintiffs are entitled to a permanent injunction, restraining Abbott from engaging in additional anticompetitive conduct, to judgment pursuant to 15 U.S.C. § 15, and to recover the costs and expenses of this action, including reasonable attorneys' fees.

SECOND CAUSE OF ACTION (Fraudulent, Unfair, and Deceptive Business Practices) (California Business and Professions Code § 17200, et seq.)

- 48. Plaintiffs incorporate allegations set forth above, as if fully stated here. This cause of action is brought on behalf of propounded class members who reside in the state of California.
- 49. Beginning on a date unknown to Plaintiffs but at least as early as December 2003 and continuing up to and including the date of the filing of this First Amended Complaint, Abbott committed and continues to commit acts of unfair competition as defined by California Business and Professions Code § 17200, et seq., by engaging in the acts and practices alleged above.
- 50. The acts, omissions, and practices alleged in this First Amended Complaint constitute a continuous course of unfair, unlawful, and/or fraudulent business practices within the meaning of California Business and Professions Code § 17200, et seq., including but in no way limited to the following:
 - a. The violations of Section 2 of the Sherman Act set forth above; and

- b. Other unfair, unconscionable, misleading, or fraudulent conduct as alleged above.
- 51. Plaintiffs and each class member are entitled to full restitution and/or disgorgement of all revenues, earnings, profits, compensation, and benefits obtained by Abbott as a result of the alleged unfair or unlawful business practices.
- 52. The illegal conduct alleged in this First Amended Complaint is continuing, and there is no indication that Abbott will not continue this conduct into the future.
- 53. Abbott's unlawful and unfair business practices have injured, and present a continuing threat of injury, to members of the public in that Abbott's conduct has restrained competition and has caused and continues to cause Plaintiffs and class members to pay supracompetitive and artificially inflated prices for Norvir.
- 54. As alleged in this First Amended Complaint, Abbott has been unjustly enriched as a result of its wrongful conduct and by its unfair competition.
- 55. For that reason, Plaintiffs and class members are entitled to equitable relief including restitution and/or disgorgement of all revenues, earnings, compensation, profits, and benefits obtained as a result of those business practices, as provided under California Business and Professions Code §§ 17203 and 17204.

THIRD CAUSE OF ACTION (Unjust Enrichment)

- 56. Plaintiffs incorporate allegations set forth above, as if fully stated here.
- 57. Abbott benefited from its unlawful acts through the receipt of overpayments by Plaintiffs and other class members. It would be inequitable for Abbott to be permitted to retain the benefit of the overpayments, which were conferred by Plaintiffs and class members.
- 58. Plaintiff and class members are entitled to the establishment of a constructive trust consisting of the benefit to Abbott of such overpayments from which Plaintiffs and class members may make claims on a pro-rata basis for restitution.

PRAYER FOR RELIEF

WHERFORE, Plaintiffs pray:

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|-----|--|-----------------|---|-------|--|
| 1 | 1. | That this actio | n be declared a class action under Rule 23 of the Federal Rule | es of | |
| 2 | Civil Procedure; | | | | |
| 3 | 2. | That Abbott's | conduct be declared a violation of Section 2 of the Sherman Act, | , the | |
| 4 | California Unfair Business Practices Act, and common law as alleged in this First Amende | | | | |
| 5 | Complaint; | | | | |
| 6 | 3. | That injunctive | relief be ordered, preventing and restraining Abbott and all pers | sons | |
| 7 | acting on its behalf from further engaging in the unlawful acts alleged in this First Amended | | | | |
| . 8 | Complaint; | | | | |
| 9 | 4. | That Plaintiffs | and class members be awarded restitution and or disgorgement of | fall | |
| 10 | revenues, profits, and benefits obtained as a result of Abbott's conduct; | | | | |
| 11 | 5. That the Court establish a constructive trust consisting of any benefit obtained by | | | | |
| 12 | Abbott as a result of its conduct, from which Plaintiffs may make claims for restitution; | | | | |
| 13 | 6. | | and class members be awarded costs, interest, expenses, a | and | |
| 14 | reasonable attorneys' and experts' fees incurred in connection with this action; and | | | | |
| 15 | 7. Such further relief as this Court deems necessary and appropriate. | | | | |
| 16 | | | | | |
| 17 | JURY DEMAND Discrepant to Park 28(h) of the Federal Park C C 1 Park 100 to | | | _ 1. | |
| 18 | Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Plaintiffs hereby respectfully demand a trial by jury. | | | гру | |
| | | | | | |
| 19 | DATED: June | e 10, 2004 | BERMAN DEVALERIO PEASE TABACCO BURT & PUCILLO | | |
| 20 | | | | | |
| 21 | | • | Sharon T. Maier | | |
| 22 | | | Joseph J. Tabacco, Jr. Michael W. Stocker | | |
| 23 | | | 425 California Street, Ste. 2100 | | |
| 24 | | | San Francisco, California 94104 Telephone: 415 433-3200 | | |
| 25 | | | Fax: 415 433-6382 | | |
| 26 | | | | | |
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R. Scott Palmer Berman DeValerio Pease Tabacco Burt & 2 Pucillo 3 515 North Flager Drive Suite 1701 4 West Palm Beach, Florida 33401 Telephone: 561 835-9400 5 Fax: 561 835-0322 6 Peter A. Pease 7 Kathleen Donovan-Maher Berman DeValerio Pease Tabacco Burt & 8 Pucillo One Liberty Square 9 Boston, Massachusetts 02109 10 Telephone: 671 524-8300 Fax: 617 542-1194 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 1.3

CERTIFICATE OF SERVICE

The above signed person hereby certifies that on date indicated in the attached pleading, I filed the attached pleading on behalf of Plaintiffs and made service on counsel of record in this matter by making an electronic filing with the Clerk of Court, using the CM/ECF system which will send notification of such filing(s) to the following persons:

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Gail Susan Greenwood ggreenwood@winston.com,

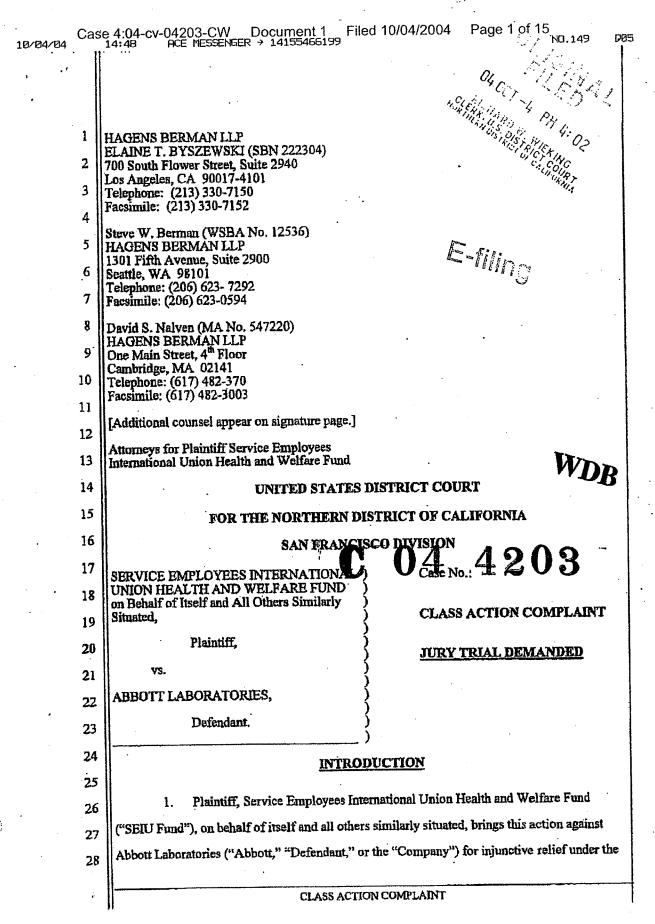
Sharon T. Maier smaier@bermanesq.com

Michael Walter Stocker mstocker@bermanesq.com,

Joseph J. Tabacco jtabacco@bermanesq.com

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EXHIBIT B



Case 4:04-cv-01511-CW Document 601 Filed 08/13/08 Page 27 of 98 Filed 10/04/2004 Page 2 of 15 Case 4:04-cv-04203-CW Document 1 PØ6 NO.149 ACE MESSENGER + 14155466199 10/04/04 antitrust laws of the United States and for restitution and/or disgorgement under California 1 Business and Professions Code Section 17200, et seq., and common law. 2 .3 JURISDICTION 4 This Court has federal question subject matter jurisdiction over this action 2. 5 pursuant to 28 U.S.C. §§ 1331 and 1337 and by Section 4 of the Clayton Act, 15 U.S.C. § 15(a). 6 This Court has supplemental jurisdiction over the state law and common law claims pursuant to 7 28 U.S.C. § 1367. 8 VENUE AND INTRADISTRICT ASSIGNMENT .9 Defendant transacts business, maintains offices, or is found within the state of 10 California. The interstate commerce described in this Complaint is carried on, in part, within this 11 District. Venue is proper in this District pursuant to the provisions of 15 U.S.C. §§ 22 and 28 12 U.S.C. § 1391. Moreover, the interstate commerce described in this Complaint is carried on, in 13 part, within the county of San Francisco, which is located within the San Francisco Division, 14 pursuant to Local Rule 3-6(d). 15 PLAINTIFFS 16 Plaintiff SEIU Fund is a self-funded, multi-employer health and welfare fund 17 organized under ERISA. The SEIU Fund has between 7,000 and 8,000 covered lives and serves 18 members of SEIU local unions, some SEIU local staff and all SEIU international staff in 19 locations throughout the United States. The SEIU Fund is administered by a joint board of 20 trustees with equal numbers of union and employer trustees. The SEIU Fund is a third-party 21 payor which pays all or part of its members' prescription drug costs. 22

DEFENDANT

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5. Abbott is a corporation organized, existing, and doing business under the laws of the state of Illinois. Its office and principal place of business is located at 100 Abbott Park Road, Abbott Park, Illinois 60064. Abbott is engaged principally in the development, manufacture, and sale of pharmaceuticals drugs and health care products and services. Abbott reported total sales

11. There are a number of PIs currently on the market, including:

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(a) Invirase (saquinavir), manufactured by Roche Laboratories, approved by the Food and Drug Administration in December 1995;

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(b) Crixivan (indinavir), manufactured by Merck, approved March 1995;

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Case 4:04-cv-04203-CW Document 1 Filed 10/04/2004 Page 4 of 15 P08 NO.149 10/04/04 Norvir® (ritonavir), manufactured by Abbott, approved March 1996; (c) 1 Viracept® (nelfinavir), manufactured by Agouron Pharmaceuticals, (d) 2 approved March 1997; 3 Fortovase® (a saquinavir reformulation), manufactured by Roche (e) 4 Laboratories, approved November 1997; 5 Agenerase® (amprenavir), manufactured by GlaxoSmithKline, approved (f) 6 April 1999; 7 Kaletra® (the PI lopinavir boosted by ritonavir), manufactured by Abbott, (g) 8 approved September 2000; 9 Revataz® (atazanavir), manufactured by Bristol-Myers Squibb, approved 10 (P) June, 2003; and 11 Lexiva® (fosamprenavir), manufactured by GlaxoSmithKline, approved **(i)** 12 October 2003. 13 Each of these PIs, like any anti-HIV drug, will eventually lose efficacy as the 12. 14 virus develops resistance to it. When such resistance occurs, the failed PI must be replaced with 15 another PI that is able to overcome the virus's resistance. Because successive PI regimes must 16 be used in a sequence carefully calibrated to reflect the virus's evolving mutations in individual 17 patients, preserving a maximum number of PI treatment options for physicians to choose from is 18 of paramount importance to the survival of people with HIV. 19 Different patients require different combination therapies and medicines 20 13. depending on, among other things, whether the patient has developed resistance to some 21 medications, side effects of a particular medicine, pregnancy, interactions with other drugs and 22 the effect of drugs on different resulting illnesses. No single PI is directly and completely 23 interchangeable with any other PI in any particular patient. 24 Norvir® is a drug parented, produced, distributed, and sold by Abbott. Abbott 25 developed Norvir® with the assistance of a National Institutes of Health grant and spent only 26 about \$15 million of its own funds on pre-approval clinical trials for the drug. Abbott is the sole 27 28

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maker of Norvir[®], and there are no generics or functionally equivalent formulations on the market. By the end of 2001, Norvir[®] had generated cumulative sales for Abbott of more than \$1 billion (more than sixty times the estimated cost of its pre-approval outlays). Securities analysts have estimated that, even without the price increase that is the subject of this Complaint, Norvir[®] would generate more than \$2 billion for Abbott over the next ten years.

- for use as a stand-alone drug or for use in combination with other PIs. Serious side effects prevented Norvir® from ever being successfully marketed as a PI. However, small doses of the drug were found to dramatically improve blood levels of other PIs, decreasing the side effects associated with those drugs and "boosting" the antiviral effect of other PIs against even resistant strains of HIV. For such boosting purposes, there is no substitute for Norvir®. The "Booster Market" thus consists of the market for Norvir®, while the "Boosted Market" consists of the market for PIs only when they are prescribed together with Norvir® as a booster. Other advantages of Norvir®-boosted PI regimens over regimens without Norvir® include convenience in terms of pill burden and reduction of food restrictions for patients, both important factors in ensuring adherence to antiretroviral therapy.
 - the use of boosted PI regimens, especially for patients who experience failure of treatment regimens combining PIs with other anti-HIV drugs. Such treatment failures are marked by the emergence of drug-resistant mutations that limit the benefit of other drugs in the future, because of cross-resistance between HIV medications. When patients experience failure of initial boosted PI regimens, there is no evidence of PI resistance and, moreover, there is less resistance to the other drugs in the regimen. Hence, by using Norvir® to boost PI regimens, physicians can maximize the treatment options remaining for the patients experiencing treatment failure.
 - 17. In addition to Norvir[®], Abbott also markets its own Norvir[®]-boosted PI, Kaletra[®].

 Kaletra[®] consists of Abbott's PI lopinavir, combined in pill form with Norvir[®] as a boosting

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Case 4:04-cv-04203-CW Document 1 Filed 10/04/2004 Page 6 of 15
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agent. Kaletra has significant side effects, however, most notably hyperlipidemia, rendering patients significantly more vulnerable to heart attacks and strokes.

- 18. Prescriptions for Kaletra[®] rose steadily after its September 2000 introduction, and by June 2003, new prescriptions and total sales of the drug had reached an all-time high, securing Kaletra[®] an approximate 75% share of the Boosted Market. However, Kaletra[®]'s domination of the Boosted Market was about to be seriously threatened.
- 19. With the June 2003 introduction of Bristol-Myers Squibb's competing PI, Reyataz, a new PI boosted by Norvir®, Kaletra®'s share of new PI prescriptions began a precipitous decline. By October 2003, the press reported that Kaletra® had "topped out." Furthermore, Kaletra® prescriptions, as a proportion of the Boosted Market, began to plummet in the two months following the introduction of Reyataz. To make matters worse, GlaxoSmithKline introduced Lexiva in October 2003, another PI boosted by Norvir®. Both Reyataz and Lexiva began to make steady inroads against Kaletra®'s boosted PI market share.
- 20. Abbott acted quickly to stanch these losses and maintain its dominant position in the Boosted Market. On December 3, 2003, barely five weeks after the release of GlaxoSmithKline's Lexiva and more than <u>seven years</u> after Norvir[®]'s introduction into the market, Abbott abruptly announced that it was raising the wholesale price of Norvir[®] from \$205.74 to \$1,028.71 for 120 100 mg capsules an increase of approximately 478%.
- 21. By means of this staggering price hike, Abbott added drastically to the cost of regimens using Norvir[®] to boost competing PIs. The annual cost of the Norvir[®] needed to boost these drugs increased by \$6,258 per year for PIs such as Lexiva requiring twice-daily doses of Norvir[®]. For Tipranovir[®], a PI currently in development by Boehringer-Ingleheim, the optimal Norvir[®] booster dose would increase by more than \$12,000 per year.
- 22. In a coup de grace against competitors' Pls, Abbott did not raise the price of the Norvir® used in its own Kaletra®. As a result, Kaletra® became the least expensive boosted regimen in the Boosted Market. By leveraging its power in the Booster Market, Abbott unlawfully maintained or extended its monopoly in the Boosted Market.

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27 28 Case 4:04-cv-04203-CW Filed 10/04/2004 Page 8 of 15 Document 1

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(c) influence the pricing patterns of other manufacturers of HIV/AIDS medications; and

- (d) adversely affect Medicare beneficiaries with HIV who, despite the recently adopted program expansion, may be unable to afford the high costs associated with receiving the new prescription drug benefit.
- The effects of Abbott's anticompetitive activities are already being felt by an 26. extraordinarily vulnerable population. At least one hospital has now revised its formulary - the list of preferred drugs that physicians may use - because of cost, to give preference to Kaletra® and restrict physicians' options to use other drugs.
- Such a cost-based consequence, however, carries with it dire physical 27. consequences. Not only does switching to Kaletra® cut short the remaining utility of patients' current non-Abbott PI, thus eliminating a definite period of time in which the HIV virus is not immune to their current PI therapy and they are healthy, but switching to Kaletra® also entails significant side effects, which include hyperlipidemia- rendering patients much more susceptible to heart attacks and strokes. Consequently, as a direct proximate result of Abbott's conduct, Plaintiff and the Class face irreparable injury for which there is no adequate remedy at law.

RELEVANT MARKETS

- All but one of the protease inhibitors, currently prescribed for the treatment of 28. HIV, benefit from the use of Norvir® as a "booster" in order to maximize the blood levels of the drug and minimize toxic side effects. Indeed, many public health assistance programs require the use of Norvir® as the booster for a PI regimen. Abbott has virtually a 100% share of the multimillion-dollar Booster Market in the United States.
- The Boosted Market consists of the market for PIs only when prescribed together 29. with Norvir® as a booster. Many of the PIs currently in use and all PIs in clinical trials are used and prescribed together with Norvir® as a booster. Abbott's Norvir®-boosted PI product, Kaletra®, is sold in this Boosted Market.
 - The United States is the geographical market. 30.

27 28 Case 4:04-cv-04203-CW

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Page 9 of 15

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CLASS ACTION ALLEGATIONS

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Plaintiff brings this action on its own behalf and as a class action under the 31. provisions of Rule 23(a), (b)(2), and (b)(3) of the Federal Rules of Civil Procedure on behalf of the following class:

> All persons or entities (excluding Abbott, its parents, subsidiaries, and affiliates, and governmental entities) who purchased Norvir indirectly as a booster to other PIs and who paid all or part of the cost of Norvir, from December 3, 2003 to the present (the "Class Period").

- Plaintiff does not know the exact number of class members. Due to the nature of 32. the trade and commerce involved, however, Plaintiff believes that the class members are sufficiently numerous and geographically dispersed throughout the United States such that joinder of all class members is impracticable.
- Except as to the amount of individual restitution and/or disgorgement that each 33. class member is entitled to, all relevant questions of fact and law are common to the class, including, but not limited to, the following:
- Whether Abbott unlawfully attempted to monopolize the Boosted Market (a) during the Class Period;
- Whether Abbott engaged in anticompetitive conduct in order to leverage (b) its monopoly in the Booster Market to obtain, maintain, or extend an undue monopoly in the Booster Market:
- Whether the geographic market for both protease inhibitor boosters and (c) boosted protease inhibitors is the United States;
- Whether the product market in which Abbott has a monopoly is the Booster Market;
- Whether the product market Abbott was attempting to monopolize is the (e) Boosted Market;

CLASS ACTION COMPLAINT

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- (f) Whether Abbott intended to monopolize the Boosted Market or to maintain or extend an existing monopoly on the Boosted Market;
- (g) Whether there was a dangerous probability that Abbott would succeed in monopolizing the Boosted Market;
 - (h) Whether Abbott had pro-competitive reasons for its conduct;
- (i) Whether Abbott's pricing practices constitute a continuous course of unfair, unlawful, and/or fraudulent business practices;
- (j) The effects of Abbott's attempted monopolization on prices of boosted protease inhibitors; and
- (k) The appropriate measure of restitution and/or disgorgement sustained by Plaintiff and class members.
- 34. Plaintiff is a member of the class, and Plaintiff's claims are typical of the claims of other class members. Plaintiff will fairly and adequately protect the interests of the class. Plaintiff's interests are coincident with, and not antagonistic to, those of other class members. In addition, Plaintiff is represented by counsel who are competent and experienced in the prosecution of antitrust class action litigation.
- 35. The prosecution of separate actions by individual class members would create a risk of inconsistent or varying adjudications, establishing incompatible standards of conduct for Abbott.
- 36. The questions of law and fact common to class members predominate over any questions affecting only individual members, including legal and factual issues relating to liability and damages.
- 37. A class action is superior to other methods available for the fair and efficient adjudication of this controversy. Treatment as a class action will permit a large number of similarly situated persons or entities to adjudicate their common claims in a single forum simultaneously, efficiently, and without the duplication of effort and expense that numerous individual actions would engender. Class treatment will also permit the adjudication of claims

Case 4:04-cv-04203-CW Document 1 Filed 10/04/2004 Page 11 of 15

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by many class members who could not afford individually to litigate an antitrust claim such as is asserted in this Complaint. This action likely presents no difficulties in management that would preclude its maintenance as a class action. Finally, the class is readily ascertainable.

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- 38. Plaintiff incorporates allegations set forth above, as if fully stated here.
- 39. At all relevant times, Abbott possessed a monopoly in the Booster Market.
- 40. The Booster Market and the Boosted Market constitute separate, relevant product markets.
- 41. Abbott possessed and acted with specific intent to achieve an anticompetitive purpose, including the intent to eliminate competitors from the Boosted Market and to unlawfully maintain its monopoly in the Boosted Market.
- 42. Abbott engaged in one or more of the predatory or anticompetitive acts alleged in this Complaint.
- 43. There is a dangerous probability that Abbott will be successful in achieving or in unlawfully maintaining a monopoly in the Boosted Market.
 - 44. There is no pro-competitive justification for Abbott's actions.
- 45. Abbott acted with an anticompetitive purpose resulting in an anticompetitive effect.
 - 46. Abbott's acts and conduct were committed for the following purposes:
 - (a) to eliminate competitors from the Boosted Market;
- (b) to chill the development of potentially competing PIs that require a booster such as Norvir[®]; and
- (c) to unlawfully maintain a monopoly in, or attempt to monopolize, the Boosted Market.
- 47. These acts by Abbott have restrained or prevented competition and threaten and continue to restrain and prevent competition.

Case 4:04-cv-01511-CW Document 601 Filed 08/13/08 Page 37 of 98

Document 1

Case 4:04-cv-04203-CW

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Filed 10/04/2004

Page 12 of 15

P16 NO.149 ACE MESSENGER + 14155466199 14:48 Plaintiff and class members have been injured in their business or property by 48, 1 reason of Abbott's antitrust violations. Their injury consists of being forced to pay higher prices 2 for Norvir®, which is an essential element of their HIV treatment, than would otherwise occur in 3 a fair and competitive market. Those injuries are of the type the antitrust laws were designed to 4 prevent and flow from that which makes Abbott's conduct unlawful. 5 As a consequence, Plaintiff is entitled to a permanent injunction, restraining 6 Abbott from engaging in additional anticompetitive conduct, to judgment pursuant to 15 U.S.C. 7 § 15, and to recover the costs and expenses of this action, including reasonable attorneys' fees. 8 9 SECOND CAUSE OF ACTION (Unfair, Unlawful, and Fraudulent Business Practices) 10 (California Business and Professions Code § 17200, et seq.) iı Plaintiff incorporates the allegations set forth above, as if fully stated here. This 12 cause of action is brought on behalf of propounded class members who reside in the state of 13 14 California. Beginning on a date unknown to Plaintiff but at least as early as December 2003 15 51. and continuing up to and including the date of the filing of this Complaint, Abbott committed 16 and continues to commit acts of unfair competition as defined by California Business and 17 Professions Code § 17200, et seq., by engaging in the acts and practices alleged above. 18 The acts, omissions, and practices alleged in this Complaint constitute a 19 continuous course of unfair, unlawful, and/or fraudulent business practices within the meaning of 20 California Business and Professions Code § 17200, et seq., including but in no way limited to the 21 22 following: The violations of Section 2 of the Sherman Act set forth above; and 23 (a) Other unfair, unconscionable, misleading, or fraudulent conduct as alleged 24 **(b)** 25 above. 26 27 28 CLASS ACTION COMPLAINT

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Filed 10/04/2004 Page 13 of 15

Case 4:04-cv-04203-CW NO.149 P17 ACE MESSENGER → 14155466199 14:48 Plaintiff and each class member are entitled to full restitution and/or disgorgement 53. of all revenues, earnings, profits, compensation, and benefits obtained by Abbott as a result of the alleged unfair or unlawful business practices. The illegal conduct alleged in this Complaint is continuing, and there is no indication that Abbott will not continue this conduct into the future. Abbott's unlawful and unfair business practices have injured, and present a continuing threat of injury, to members of the public in that Abbott's conduct has restrained competition and has caused and continues to cause Plaintiff and class members to pay supracompetitive and artificially inflated prices for Norvir. As alleged in this Complaint, Abbott has been unjustly enriched as a result of its wrongful conduct and by its unfair competition. For that reason, Plaintiff and class members are entitled to equitable relief including restitution and/or disgorgement of all revenues, earnings, compensation, profits, and 13 benefits obtained as a result of those business practices, as provided under California Business 14 and Professions Code §§ 17203 and 17204. 15 16 THIRD CAUSE OF ACTION 17 Plaintiff incorporates the allegations set forth above, as if fully stated here. 18 58. Abbott benefited from its unlawful acts through the receipt of overpayments by 19 59. Plaintiff and other class members. It would be inequitable for Abbott to be permitted to retain 20 the benefit of the overpayments, which were conferred by Plaintiff and class members. 21 Plaintiff and class members are entitled to the establishment of a constructive trust 22 60. consisting of the benefit to Abbott of such overpayments from which Plaintiff and class members 23 24 may make claims on a pro-rata basis for restitution. 25 26 27 28 CLASS ACTION COMPLAINT

Case 4:04-cv-04203-CW Document 1 Filed 10/04/2004 Page 14 of 15 NO.149 **D18** 14:48 ACE MESSENGER → 14155466199 10/04/04 PRAYER FOR RELIEF , 1 WHEREFORE, Plaintiff prays: 2 That this action be declared a class action under Rule 23 of the Federal 3 1. Rules of Civil Procedure; 4 That Abbott's conduct be declared a violation of Section 2 of the Sherman 2. 5 Act, the California Unfair Business Practices Act, and common law as alleged in this Complaint; 6 That injunctive relief be ordered, preventing and restraining Abbott and all 3. 7 persons acting on its behalf from further engaging in the unlawful acts alleged in this Complaint; 8 That Plaintiff and class members be awarded restitution and/or 9 4. disgorgement of all revenues, profits, and benefits obtained as a result of Abbott's conduct; 10 That the Court establish a constructive trust consisting of any benefit 5. 11 obtained by Abboit as a result of its conduct, from which Plaintiff and class members may make 12 claims for restitution; 13 That Plaintiff and class members be awarded costs, interest, expenses, and 6. 14 reasonable attorneys' and experts' fees incurred in connection with this action; and 15 Such further relief as this Court deems necessary and appropriate. 7. 16 JURY DEMAND 17 18 Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Plaintiff hereby 19 respectfully demands a trial by jury. 20 DATED: October 4 , 2004 21 22 HAGENS BERMAN LLP 23 24 25

700 South Flower Street, Suite 2940 Los Angeles, CA 90017-4101 Telephone: (213) 330-7150

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EXHIBIT C

Case 4:04-cv-01511-CW Document 256 Filed 07/06/2006 Page 1 of 24

IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA

IN RE ABBOTT LABORATORIES NORVIR ANTI-TRUST LITIGATION

No. C 04-1511 CW

(Consolidated Case)
No. C 04-4203 CW

ORDER DENYING
DEFENDANT'S RENEWED
MOTION FOR SUMMARY
JUDGMENT

Defendant Abbott Laboratories moves for summary judgment.

Plaintiffs John Doe 1, John Doe 2, and the Service Employees

International Union Health and Welfare Fund (SEIU) oppose the

motion. The matter was heard on April 7, 2006. Having considered
the parties' papers, the evidence cited therein and oral arguments,
the Court denies Defendant's renewed summary judgment motion.

BACKGROUND

Protease inhibitors (PIs) are considered the most potent class of drugs to combat the HIV virus. In 1996, Defendant introduced Norvir as a stand-alone PI with a daily recommended dose of 1,200

milligrams (twelve 100-mg capsules a day), priced at approximately eighteen dollars per day. Norvir is the brand name for a patented compound called ritonavir.

After Norvir's release, it was discovered that, when used in small quantities with another PI, Norvir would "boost" the antiviral properties of that PI. Not only did a small dose of Norvir, about 100 to 400 milligrams per day, make other PIs more effective and decrease side effects associated with high doses, but it also slowed down the rate at which HIV developed resistance to the effects of PIs. The use of Norvir as a "booster" has enabled HIV patients to live longer. But the use of Norvir as a booster, and not a stand-alone PI, has also meant that the average daily price of Norvir has plummeted since Norvir was first introduced, because patients need only a small daily dose of Norvir as a booster. By 2003, the average daily price of Norvir was \$1.71.

In 2000, Defendant introduced Kaletra, a pill containing the protease inhibitor lopinavir and Norvir. Although effective and widely used, Kaletra had significant side effects for some patients.

In 2003, two new PIs, Bristol-Myers Squibb's Reyataz and GlaxoSmithKline's Lexiva, were about to be introduced to the market. Studies showed that, when boosted with Norvir, the new PIs were as effective as Kaletra, and were more convenient. In July, 2003, Reyataz was successfully introduced to the market. As a result, Kaletra's market share fell more than Defendant anticipated. The average daily dose of Norvir also fell. Before Reyataz's release, the most common boosting dose of Norvir ranged

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Document 256

Filed 07/06/2006

Page 3 of 24

from 200 milligrams to 400 milligrams a day. Clinical trials, however, showed that a Norvir dose of only 100 milligrams a day effectively boosted Reyataz.

On December 3, 2003, Defendant raised by 400 percent the wholesale price of Norvir. Defendant contends that it raised Norvir's price so that it would be more in line with the drug's enormous clinical value. Plaintiffs contend that the Norvir price increase was an illegal attempt to achieve an anti-competitive purpose in the "boosted market," which Plaintiffs define as the market for those PIs, such as Reyataz, Lexiva and Kaletra, that are prescribed for use with Norvir as a booster. Plaintiffs sued for violations of section 2 of the Sherman Act and California Business and Professions Code section 17200.

On June 1, 2005, Defendant filed a motion for summary judgment. On June 27, 2005, Plaintiffs filed a Rule 56(f) response. The Court granted Plaintiffs' Rule 56(f) motion and denied Defendant's motion for summary judgment without prejudice as premature. Following further discovery, Defendant now renews its motion for summary judgment.

LEGAL STANDARD

Summary judgment is properly granted when no genuine and disputed issues of material fact remain, and when, viewing the evidence most favorably to the non-moving party, the movant is clearly entitled to prevail as a matter of law. Fed. R. Civ. P. 56; Celotex Corp. v. Catrett, 477 U.S. 317, 322-23 (1986); Eisenberg v. Ins. Co. of N. Am., 815 F.2d 1285, 1288-89 (9th Cir. 1987).

Case 4:04-cv-01511-CW Document 601 Filed 08/13/08 Page 45 of 98

Case 4:04-cv-01511-CW Document 256 Filed 07/06/2006 Page 4 of 24

The moving party bears the burden of showing that there is no material factual dispute. Therefore, the court must regard as true the opposing party's evidence, if supported by affidavits or other evidentiary material. Celotex, 477 U.S. at 324; Eisenberg, 815 F.2d at 1289. The court must draw all reasonable inferences in favor of the party against whom summary judgment is sought.

Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587 (1986); Intel Corp. v. Hartford Accident & Indem. Co., 952 F.2d 1551, 1558 (9th Cir. 1991).

Material facts which would preclude entry of summary judgment are those which, under applicable substantive law, may affect the outcome of the case. The substantive law will identify which facts are material. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986).

Where the moving party does not bear the burden of proof on an issue at trial, the moving party may discharge its burden of production by either of two methods. Nissan Fire & Marine Ins.

Co., Ltd., v. Fritz Cos., Inc., 210 F.3d 1099, 1106 (9th Cir. 2000).

The moving party may produce evidence negating an essential element of the nonmoving party's case, or, after suitable discovery, the moving party may show that the nonmoving party does not have enough evidence of an essential element of its claim or defense to carry its ultimate burden of persuasion at trial.

Id.

If the moving party discharges its burden by showing an absence of evidence to support an essential element of a claim or defense, it is not required to produce evidence showing the absence

of a material fact on such issues, or to support its motion with evidence negating the non-moving party's claim. Id.; see also Lujan v. Nat'l Wildlife Fed'n, 497 U.S. 871, 885 (1990); Bhan v. NME Hosps., Inc., 929 F.2d 1404, 1409 (9th Cir. 1991). If the moving party shows an absence of evidence to support the non-moving party's case, the burden then shifts to the non-moving party to produce "specific evidence, through affidavits or admissible discovery material, to show that the dispute exists." Bhan, 929 F.2d at 1409.

If the moving party discharges its burden by negating an essential element of the non-moving party's claim or defense, it must produce affirmative evidence of such negation. Nissan, 210 F.3d at 1105. If the moving party produces such evidence, the burden then shifts to the non-moving party to produce specific evidence to show that a dispute of material fact exists. Id.

If the moving party does not meet its initial burden of production by either method, the non-moving party is under no obligation to offer any evidence in support of its opposition. <u>Id.</u> This is true even though the non-moving party bears the ultimate burden of persuasion at trial. <u>Id.</u> at 1107.

Where the moving party bears the burden of proof on an issue at trial, it must, in order to discharge its burden of showing that no genuine issue of material fact remains, make a <u>prima facie</u> showing in support of its position on that issue. <u>UA Local 343 v.</u>

<u>Nor-Cal Plumbing, Inc.</u>, 48 F.3d 1465, 1471 (9th Cir. 1994). That is, the moving party must present evidence that, if uncontroverted at trial, would entitle it to prevail on that issue. <u>Id.</u>; <u>see also</u>

Int'l Shortstop, Inc. v. Rally's, Inc., 939 F.2d 1257, 1264-65 (5th Cir. 1991). Once it has done so, the non-moving party must set forth specific facts controverting the moving party's prima facie case. UA Local 343, 48 F.3d at 1471. The non-moving party's "burden of contradicting [the moving party's] evidence is not negligible." Id. This standard does not change merely because resolution of the relevant issue is "highly fact specific." Id. DISCUSSION

I. Plaintiffs' Claims under the Sherman Act

Defendant argues that Plaintiffs cannot satisfy the necessary elements of their monopolization or attempted monopolization claims under the Sherman Act. Specifically, Defendant argues that Plaintiffs' claims fail as a matter of law because (1) Kaletra's falling market share establishes a lack of monopoly power,

- (2) Plaintiffs cannot establish anti-competitive conduct,
- (3) Plaintiffs cannot establish an anti-trust injury and
- (4) Defendant's patents, which it contends cover the boosted market, provide immunity from Plaintiffs' anti-trust claims.

A monopolization claim under section 2 of the Sherman Act requires a plaintiff to prove "(1) possession of monopoly power in the relevant market, (2) willful acquisition or maintenance of that power, and (3) causal 'antitrust injury." Rutman Wine Co. v.

E. & J. Gallo Winery, 829 F.2d 729, 736 (9th Cir. 1987). An attempted monopolization claim requires "(1) specific intent to control prices or destroy competition in the relevant market,

(2) predatory or anti-competitive conduct directed to accomplishing the unlawful purpose, and (3) a dangerous probability of success."

United States District Court

For the Northern District of California

A. Monopoly Power

Monopoly power can be shown through either direct or circumstantial evidence. <u>See Rebel Oil Co., Inc. v. Atlantic Richfield Co.</u>, 51 F.3d 1421, 1434 (9th Cir. 1995). Plaintiffs contend that they have proferred both kinds of evidence that Defendant has monopoly power in the boosted market.

1. Direct Evidence

Plaintiffs present evidence showing that Defendant's 400 percent increase of Norvir's price had a significant impact on the boosted market. One of Defendant's competitors in the boosted market, GlaxoSmithKline, the maker of Lexiva, believed that Lexiva's failure to meet forecasted expectations was due, in part, to the Norvir price hike. Professor Douglas F. Greer, Plaintiffs' expert, notes that, in the absence of the price hike, Defendant anticipated that Kaletra's market share would decline by ten percent in 2004. But, according to Professor Greer, following the price increase in December, 2003, sales of Kaletra essentially remained stable. Furthermore, Defendant's documents show that it knew that raising Norvir's price could result in formularies restricting access to Norvir and a potential increase in Kaletra's market share. As a result of increasing the price of Norvir, Defendant believed that at least one of its competitors in the

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Case 4:04-cv-01511-CW Document 256 Filed 07/06/2006 Page 8 of 24

boosted market "will need to give away significant rebates to be cost neutral to Kaletra."

Defendant responds that this is not direct evidence of monopoly power. Defendant contends that direct evidence requires proof that it restricted output to produce "supracompetitive prices." The case Defendant cites, however, involved predatory pricing, which is not at issue in this case. See Rebel Oil., 51 F.3d at 1434. As the court stated in Forsyth v. Humana, Inc., 114 F.3d 1467, 1475 (9th Cir. 1997), "Direct proof of market power may be shown by evidence of restricted output and supracompetitive prices." But it does not have to be shown by such evidence. It can also be shown by "'injury to competition which a competitor with market power may inflict, and thus, of the actual exercise of market power.'" Id. (quoting Rebel Oil., 51 F.3d at 1434). Plaintiffs provide such direct proof, thus creating a material factual dispute. See Confederated Tribes of Siletz Indians of Or. v. Weyerhaeuser Co., 411 F.3d 1030, 1043 (9th Cir. 2005) (defendant's employees' testimony that the defendant had power to influence prices and used that power was direct evidence).

2. Circumstantial Evidence

To demonstrate monopoly power by circumstantial evidence, Plaintiffs must "(1) define the relevant market, (2) show that the defendant owns a dominant share of that market, and (3) show that there are significant barriers to entry." Rebel Oil, 51 F.3d at 1434.

The relevant market is the boosted market. Both parties agree that, to establish a <u>prima facie</u> case of market power, courts

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generally require a sixty-five percent market share. See, e.g., Image Technical, 125 F.3d at 1206. Professor Greer finds that Defendant's share of the boosted market is no longer falling and presently is seventy-three percent. Defendant attacks this figure: its vice-president contends that its share in the boosted market has fallen from seventy-seven percent in July, 2003, to forty-seven percent in November, 2005, well below the required sixty-five percent. In calculating Defendant's market share in the boosted market, Professor Greer contends that both of Defendant's products in that market must be accounted for: Kaletra and Norvir. Court cannot determine, on a motion for summary judgment, who is providing the correct market share percentage, Plaintiff's expert economist or Defendant's vice-president; that must be determined by a jury.

Finally, circumstantial evidence of monopoly power also requires a showing that there are significant barriers to entry into the relevant market. Plaintiffs note that the cost of bringing a new PI to the market exceeds \$300 million dollars and takes several years. It took GlaxoSmithKline over seven years to bring its PI, Lexiva, to the market. In addition, patents are a common entry barrier. Id. at 1208.

Defendant responds that there are no significant barriers, noting that two PIs created by its competitor are currently being evaluated in clinical trials. Defendant further notes that it costs hundreds of millions of dollars for any company to bring a new PI to the market; the fact that entry requires an enormous expenditure of funds does not by itself constitute a barrier to

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Los Angeles Land Co. v. Brunswick Corp., 6 F.3d 1422, 1428 (9th Cir. 1993). The hundreds of millions of dollars required, combined with the patents already in the field and the years required to get a product to the market, however, create a material factual dispute whether there are significant barriers to entry into the boosted market.

Anti-competitive Conduct В.

Defendant contends that, in order to offer evidence of anticompetitive conduct, Plaintiffs must show that Defendant impaired the opportunities of its rivals in an unnecessarily restrictive See Aspen Skiing Co. v. Aspen Highlands Skiing Corp., 472 U.S. 585 (1985). That is incorrect. Aspen Skiing Co., involving a defendant's refusal to cooperate with its smaller rival, is This is not a failure to deal, or failure to cooperate, case. Nor is this a case seeking liability under the Sherman Act for a defendant merely "charging too much." As this Court has recognized in its prior orders, Plaintiffs allege, relying on the monopoly leveraging theory recognized in Image Technical, 125 F.3d at 1208, that, while Defendant holds patents in the booster market, Defendant's Norvir price increase constituted impermissible anti-competitive conduct in the boosted market. See Image Technical, 125 F.3d at 1216 ("a monopolist who acquires a dominant position in one market through patents and copyrights may violate § 2 if the monopolist exploits that dominant position to enhance a monopoly in another market").

Plaintiffs provide evidence that Defendant abused its patent rights to Norvir to maintain its monopoly in the boosted market.

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According to Plaintiffs' expert, although the 400 percent price increase did not raise Kaletra's market share, it raised its market share substantially above what it would have been absent the price increase. Even Defendant's calculations show that Kaletra remains the most prescribed PI in the boosted market. Defendant realized that drastically increasing the price of Norvir had the potential to increase Kaletra's market share in the boosted market; that potential was listed among the "pros" for raising Norvir's price.

Defendant offers evidence that its competitors are thriving. Defendant's data shows that, from July, 2003 to November, 2005, Reyataz's market share increased from 5.7 percent to 33.8 percent; Lexiva has achieved a 11.6 percent market share since it entered the market in November, 2004. Defendant notes that two of its competitors have raised the price of their PIs since it raised Norvir's price: GlaxoSmithKline twice raised Lexiva's price by a total of about ten percent and Bristol-Myers twice raised Reyataz's price by a total of about eight percent. Although this evidence may weaken Plaintiffs' case, it does not dispel the material factual dispute regarding whether Defendant engaged in anticompetitive conduct when it raised Norvir's price by 400 percent.

Anti-trust Injury C.

To show an anti-trust injury, Plaintiffs must prove that their loss flows from an anti-competitive aspect or effect of Defendant's See, e.g., Rebel Oil, 51 F.3d at 1433 (noting that "it behavior. is inimical to the antitrust laws to award damages for losses stemming from acts that do not hurt competition"). Defendant argues that Plaintiffs fail to show an anti-trust injury because

Case 4:04-cv-01511-CW Document 256 Filed 07/06/2006 Page 12 of 24

paying a high price for a patented drug is not an anti-trust injury. However, Plaintiffs provide their expert's finding that Defendant's price increase harms HIV patients by creating another barrier to entry that hinders the introduction of new PIs from Defendant's competitors, and, therefore, provide evidence of anti-trust injury.

Because there are disputed issues of material fact, the Court denies Defendant's motion for summary judgment that Plaintiffs have failed to establish a lack of monopoly power, anti-competitive conduct or anti-trust injury.

D. Asserted Anti-trust Immunity Based on Defendant's Patents
Defendant asserts that, even if it were capable of
monopolizing the boosted market, its patent defense still ends this
case in its favor. See Image Technical, 125 F.3d at 1215

("Legally, a patent amounts to a permissible monopoly over the
protected work."). Defendant argues that its patents cover the
boosted market, as well as the booster market, and that, even if
its patents do not cover boosted market, its decision to raise
Norvir's price was not a pretext to monopolize the market.

Plaintiffs disagree, noting that Defendant bears the burden of
establishing its patent immunity affirmative defense. See ITSI

Defendant argues that, under <u>Image Technical</u>, it is entitled to summary judgment because there is no evidence of any anticompetitive intent that would rebut the presumption that its conduct was legitimate. <u>See</u> 125 F.3d at 1218-19. Defendant presents evidence that its decision to raise Norvir's price was a legitimate business decision. But Plaintiffs present evidence of anti-competitive intent, suggesting that Defendant's "legitimate business decision" was a pretext to monopolize, or attempt to monopolize, the market. Thus, summary judgment on this issue is not appropriate.

Case 4:04-cv-01511-CW Document 256 Filed 07/06/2006

HIV.

T.V. Productions, Inc. v. Agric. Associations, 3 F.3d 1289, 1291 (9th Cir. 1993) (an affirmative defense must be proved by the party that asserts it). According to Plaintiffs, Defendant fails to carry its burden because Defendant impliedly licensed patients to use Norvir as a booster and because its U.S. Patent No. 6,037,157 (the '157 patent) is invalid and its prosecution history shows that it does not encompass the use of Norvir with other PIs to treat

Page 13 of 24

1. Defendant's Patents and the Boosted Market

Defendant notes that in <u>Image Technology</u> the defendant had patent rights over only one of the relevant markets; the plaintiffs alleged that the defendant's refusal to sell a patented product, the photocopier parts, was an attempt to monopolize an unpatented service market for repairing photocopiers. Defendant contends that, unlike the defendant in <u>Image Technology</u>, it has patents that cover both booster and boosted markets. Although Defendant states that it has at least two patents, the '157 patent and U.S. Patent No. 5,886,036 (the '036 patent), that plainly cover the boosted market, in the argument section of its moving papers, it focuses only on the '157 patent.

According to Defendant, the '157 patent claims a "method for improving" the efficacy of another protease inhibitor by administering a "therapeutically effective amount of a combination of said drug" and Norvir, and thus covers the boosted market. But, as Plaintiffs note, in proffering its proposed claim construction of the '157 patent, Defendant only paraphrases claim 1, which provides,

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27 28 A method for improving the pharmacokinetics of a drug which is metabolized by cytochrome P450 monooxygenase comprising administering to a human in need of such treatment a therapeutically effective amount of a combination of said drug or a pharmaceutically acceptable salt thereof and ritonavir or a pharmaceutically acceptable salt thereof.

Park Dec., Ex. C at 13:42-48.

The Federal Circuit has held that a patent's "prosecution history must be considered in construing claims." Pall Corp. v. PTI Techs., Inc., 259 F.3d 1383, 1391 (Fed. Cir. 2001), vacated and remanded on other grounds, 535 U.S. 1109 (2002). As the court explained in Southwall Technologies, Inc. v. Cardinal IG Co., 54 F.3d 1570 (Fed. Cir. 1995),

Arguments and amendments made during the prosecution of a patent application and other aspects of the prosecution history, as well as the specification and other claims, must be examined to determine the meaning of terms in the claims. The prosecution history limits the interpretation of claim terms so as to exclude any interpretation that was disclaimed during prosecution. Claims may not be construed one way in order to obtain their allowance and in a different way against accused infringers.

54 F.3d at 1576 (citations omitted).

The patent examiner twice rejected the '157 patent for obviousness. First, the examiner found that it would have been obvious to one skilled in the art to combine Norvir "with other HIV protease inhibitors for treating an HIV infection" because another of Defendant's patents, U.S. Patent No. 5,552,558 (the '558 patent), suggests this. Second Weibe Dec., Ex. D at 2. Defendant did not dispute this. Instead, Defendant asserted that the '558 patent "neither discloses or suggests (1) that ritonavir inhibits cytochrome P450 monooxygenase or (2) that ritonavir improves the pharmacokinetics of compounds which are metabolized by cytochrome

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P450 monooxygenase" and therefore the '558 patent "does not make unpatentable the presently claimed invention." Id., Ex. E at 1-2. The patent examiner disagreed and for the second time rejected the '157 patent as obvious, stating that "one skilled in the art would have been motivated to use the combination of Ritonavir and another HIV protease inhibitor for treating an HIV infection since the utility is the same, i.e., increase efficacy of combination treatment and [the '558 patent] teaches using combination treatment for an HIV infection." Id., Ex. I at 2. Again, Defendant did not dispute this and instead focused on cytochrome P450 monooxygenase. In addition, Defendant amended its '157 patent application to cancel its express claims of use of Norvir with other PIs to treat HIV, although Defendant later refiled those canceled claims as a separate patent. Plaintiffs contend that, because Defendant did not argue during the patent prosecution that the patent covered Norvir's use as a booster, it should now be excluded from arguing See Standard Oil Co. v. Am. Cyanamid Co., 774 F.2d that it does. 448, 452-53 (Fed. Cir. 1985) (noting that "the prosecution history (or file wrapper) limits the interpretation of claims so as to exclude any interpretation that may have been disclaimed or

Defendant responds that the '157 patent clearly covers the boosted market, arguing that the scope of a claim can be limited through disclaimer only where such a disclaimer is clear and unmistakable, determined by what "a competitor would reasonably believe that the applicant had surrendered." Tech. Licensing Corp. V. AV Techs. LLC, 2005 U.S. Dist. LEXIS 40717, *26 (E.D. Cal.

disavowed during prosecution in order to obtain claim allowance").

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2005). Because five of its competitors took a license to the '157 patent, Defendant argues that its competitors do not believe that it disclaimed coverage over PI boosting. That argument is not convincing. Those competitors could have decided it was to their advantage to get a license, even while believing that Defendant did make a clear disclaimer. Defendant notes that most PIs are metabolized by cytochrome P450 monooxygenase. It could well be that the competitors whose PIs are metabolized by cytochrome P450 monooxygenase are the five who obtained a license. Defendant also argues that it did not disclaim Norvir's boosting use with other PIs because it later obtained a patent based on the cancelled claims of the '157 patent. This argument is likewise not convincing. In light of the prosecution history of the '157 patent, the Court is persuaded that Defendant disclaimed the use of Norvir with other PIs to treat HIV.

Nor is the Court persuaded that Defendant is entitled to immunity provided by its other patents that cover the boosted market. Defendant has the burden regarding its affirmative defense. It not meet its burden by referring to a case where another court found that it had patents covering Norvir's use in both the booster and boosted market. See Schor v. Abbott Labs., 378 F. Supp. 2d 850, 859 (N.D. Ill. 2005). In that case, unlike in this case, the plaintiff did not challenge Defendant's assertion that its patents explicitly cover the use of Norvir as a booster in combination with another PI. Defendant must do more than name a few of its patents, quote a couple of lines from each patent, and assert that each patent clearly covers the boosted market.

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27 28 the Court denies Defendant summary judgment that its patents cover the boosted market. This issue remains in dispute.

2. Implied License

Plaintiffs contend that, even if Defendant's patents covered the boosted market, those patents would not give Defendant the power to exclude competitors from the boosted market because Defendant impliedly licenses patients to use Norvir as a booster. If patients are not potential or actual infringers, Plaintiffs contend that Defendant's competitors are not infringers. Thus, Defendant cannot sell Norvir for boosting use and then exclude competitors from the boosted market.

An implied license signifies a patentee's waiver of the statutory right to exclude others from making, using or selling the Wang Labs., Inc. v. Mitsubishi Electronics patented invention. Am., Inc., 103 F.3d 1571, 1580 (Fed. Cir. 1997). Implied licenses arise by acquiescence, by conduct, by equitable estoppel, or by legal estoppel. The Federal Circuit notes that the different ways in which implied licenses can arise "describe not different kinds of licenses, but rather different categories of conduct which lead to the same conclusion: an implied license." Id. This Court has previously stated that, to prevail on an implied license defense,

the alleged infringer must show both that the device sold by the patentee has no reasonable, non-infringing use, and that "the circumstances plainly indicate that the grant of a license should be inferred." This second requirement will be met when the elements of equitable estoppel are satisfied. other words, if the patentee's actions lead the alleged infringer to believe that it has a license to use the invention and, in reliance on those actions, the alleged infringer practices the patent, the court may determine that the patentee's actions created an implied license.

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LG Electronics, Inc. v. Asustek Computer, Inc., 2002 WL 31996860, *13 (N.D. Cal.) (citations omitted; quoting Bandag, Inc. v. Al Bolser's Tire Stores, Inc., 750 F.2d 903, 925 (Fed. Cir. 1984)).

Defendant responds that the cases Plaintiff cites discuss implied licenses as a defense to patent infringement charges, not as a defense to anti-trust charges. Plaintiffs do not cite a case holding that an implied license eliminates patent immunity. Nor does Defendant cite a case holding that an implied license cannot eliminate patent immunity under anti-trust laws. In the absence of cited authority, the Court finds that an implied license can eliminate patent immunity under anti-trust laws. If Defendant has impliedly licensed Norvir's use as a booster, then it has waived its right to exclude others from using Norvir as a booster, and cannot rely on its patents to immunize its conduct from anti-trust scrutiny.

Plaintiffs provide evidence that Defendant is aware that patients use Norvir with other PIs to treat HIV and that, by its conduct, Defendant approves and encourages such use. Defendant knows that Norvir is now used almost exclusively as booster for other PIs. Mr. Jesus Leal, Defendant's former general manager, stated that "the company basically finally said" that Norvir "is not a stand-alone PI anymore, this PI is a straight booster." First Weibe Dec., Ex. H at 23:25-26:2. One-hundred milligrams of Norvir is the most commonly used boosting dosage; Defendant markets Norvir as a 100 milligram tablet in a thirty-pill bottle, which Plaintiffs note reflects the fact that many health plans permit a patient to obtain only a thirty-day supply of a drug at one time.

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Previously, Norvir was sold in a 120-pill bottle.

Defendant states that it protects its patent rights and has not given anyone an implied license to Norvir's boosting use. But Defendant's own words show otherwise. As Defendant stated in a June 4, 2004 letter to the Federal Trade Commission, "Despite having a right to do so, Abbott did not exclude anybody from taking advantage of ritonavir's boosting properties without buying Instead, Abbott has continued to allow others access to ritonavir's boosting properties by keeping Norvir on the market, even to competitors who refuse to pay a license and encourage the infringement of the patent." First Weibe Dec., Ex. B at NOR 91660 (citation omitted). Defendant notes that five of its competitors have obtained licenses, and contends that patients who buy PIs from those five competitors have the benefit of its express license agreements. Defendant's expert, Hon. Gerald J. Mossinghoff, contends that these license agreements show that Defendant has been protective of its intellectual property rights. At the hearing, Plaintiffs disagreed, arguing that the licenses, which are not in the record, prohibit sublicensing and do not expressly authorize patients to use Norvir as a booster.

Defendant also argues that Plaintiffs' implied license argument fails because they cannot show that there are no non-infringing uses for Norvir; some patients still use Norvir as a stand alone drug. See Glass Equip. Dev., Inc. v. Besten, Inc., 174 F.3d 1337, 1343 (Fed. Cir. 1999). Those patients, however, are few, and likely would not be using Defendant's thirty-pill bottle.

There is a dispute as to whether Defendant has impliedly

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licensed Norvir. This is an additional reason to deny Defendant's motion for summary judgment.

Anticipation and Obviousness

Plaintiffs also argue that Defendant's immunity defense fails because the '157 patent is invalid. Plaintiff argue that the '157 patent is anticipated by Defendant's '882 and '558 patents, and is Anticipation of a patent claim requires that a prior art reference "disclose every limitation of the claimed invention, either explicitly or inherently." Atlas Powder Co. v. Ireco, Inc., 190 F.3d 1342, 1346 (Fed. Cir. 1999). The Federal Circuit has instructed that

a prior art reference may anticipate when the claim limitation or limitations not expressly found in that reference are nonetheless inherent in it. Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claimed limitations, it anticipates. Inherency is not necessarily coterminous with the knowledge of those of ordinary skill in the art. Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer.

<u>Id</u>. at 1347.

A patent is invalid for obviousness if the differences between it and the prior art "are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art." 35 U.S.C. § 103(a). To determine if a patent is invalid for obviousness, the court must consider the scope and content of the prior art, the difference between the patented invention and the prior art, and the level of

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skill in the art. <u>Graham v. John Deere Co.</u>, 383 U.S. 1, 17 (1966); see also Crown Operations Int'l, Ltd. v. Solutia Inc., 289 F.3d 1367, 1375 (Fed. Cir. 2002). "Determination of obviousness cannot be based on the hindsight combination of components selectively culled from the prior art to fit the parameters of the patented invention." <u>ATD Corp. v. Lydall, Inc.</u>, 159 F.3d 534, 546 (Fed. Cir. 1998).

Plaintiffs contend that the '882 and '558 patents disclosed the use of Norvir with other PIs to treat HIV, and that the use of Norvir with other PIs to treat HIV was obvious under the prior art. The '882 and '558 patents both state, "Other antiviral agents to be administered in combination with [Norvir] include . . . retroviral protease inhibitors (for example HIV protease inhibitors . . . "). Second Weibe Dec., Exs. L ('558 patent at 107:67 to 108:10); M ('882 patent at 110:14-25). Claim 1 of the '882 patent states: "A method of inhibiting an HIV infection comprising administering to a human in need thereof a therapeutically effective amount of [Norvir] or a pharmaceutically acceptable salt thereof in combination with a therapeutically effective amount of another HIV protease inhibiting compound." Id., Ex. L at 112:21-29. According to Plaintiffs, inherent in the use of Norvir with other PIs disclosed in these patents is the interaction of Norvir with cytochrome P450 monooxygenase and the resulting improved pharmacokinetics that the '157 patent claims. As noted above, "the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to

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the discoverer." Atlas Powder, 190 F.3d at 1347.

Defendant first responds by arguing that it has several patents covering the boosted market and thus, even if the '157 patent is found to be invalid, its other patents would provide anti-trust immunity. But, as noted above, the Court denies Defendant summary judgment that its other patents covered the boosted market. Defendant next argues that the validity of the '157 patent is irrelevant because anti-trust immunity does not retroactively disappear if a patent is later deemed invalid. First Circuit has held that "a patentee who has a good faith belief in the validity of a patent will not be exposed to antitrust damages even if the patent proves to be invalid." CVD, Inc. v. Raytheon Co., 769 F.2d 842, 850 (1st Cir. 1985). As Plaintiffs note, however, here, they are not seeking retroactive damages for past anti-competitive conduct; instead, they seek injunctive relief for future monopolistic conduct. CVD, Inc. and other cases Defendant cites are inapposite. Because Plaintiffs seek to address future harm, the validity of Defendant's patent is relevant.

Plaintiffs must prove invalidity by clear and convincing evidence. See, e.g., Perricone v. Medicis Pharm. Corp., 432 F.3d 1368, 1372 (Fed. Cir. 2005). But, because they are only opposing Defendant's summary judgment motion, they do not need to prove invalidity by clear and convincing evidence in their opposition. Rather, they need to show that there is a dispute of fact and that there are enough facts from which a jury reasonably could find clear and convincing evidence that the '157 was anticipated and/or obvious. Plaintiffs make such a showing. This is an additional

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basis for denying Defendant's motion for summary judgment.

II. Plaintiffs' Objections to the Magistrate's Order

Case 4:04-cv-01511-CW Document 256 Filed 07/06/2006

In their discussion of the validity of the '157 patent, Plaintiffs note that they have been denied patent validity Plaintiffs filed an objection to the Magistrate Judge's discovery. January 18, 2006 Discovery Order, which denied Plaintiffs' request for discovery regarding the validity of Defendant's patents. Because of the briefing schedule, Plaintiffs had to file their opposition to Defendant's summary judgment motion before this Court could decide the merits of Plaintiffs' objections. Plaintiffs state that the Magistrate Judge viewed this Court's September 12, 2005 order, granting Plaintiffs' Rule 56(f) motion and denying Defendant's motion for summary judgment without prejudice, as susceptible to contrary interpretations. The Magistrate Judge interpreted the Court's order as providing that Plaintiffs were not entitled to discovery regarding patent validity. But the Court's order did not limit discovery; rather, it merely provided a continuance, allowing Plaintiffs additional time for discovery. Plaintiff's objections (Docket No. 177) to the Magistrate Judge's discovery order are sustained.

III. Plaintiffs' State Law Claims

The parties agree that if the anti-trust claims fail, both of Plaintiffs' State law claims fail as well. As discussed above, the anti-trust claims do not fail as a matter of law. Thus, the State law claims for unfair competition and unjust enrichment under section 17200 of the California Business and Professions Code also do not fail as a matter of law.

Case 4:04-cv-01511-CW Document 601 Filed 08/13/08 Page 65 of 98

Case 4:04-cv-01511-CW Document 256 Filed 07/06/2006 Page 24 of 24

CONCLUSION

For the foregoing reasons, Defendant's renewed motion for summary judgment motion (Docket No. 167) is DENIED.²

IT IS SO ORDERED.

Dated: 7/6/06

Claudichillen

United States District Judge

²⁶ In addition, Plaintiffs' Motion to Unseal (Docket No. 219) is DENIED. Defendant's Motion for Leave to File Supplemental Material (Docket No. 244) is also DENIED.

EXHIBIT D

SETTLEMENT AGREEMENT

It is hereby stipulated by and among the undersigned, subject to approval by United States District Court for the Northern District of California, Oakland Division ("District Court") and other express conditions, that the settlement of this Action (defined below) shall be effectuated pursuant to the terms and conditions set forth in this agreement ("Settlement Agreement") and Exhibits (attached hereto).

PREAMBLE

WHEREAS, on April 19, 2004, plaintiffs John Doe 1 ("Doe") and John Doe 2 ("Doe 2" and together with Doe, the "Individual Plaintiffs"), in their individual capacities and on behalf of a putative class, sued defendant Abbott Laboratories ("Abbott") in the District Court, under the caption *John Doe 1 et al.*, v. Abbott Laboratories, No. 04-cv-1511 (the "Doe Action"); and

WHEREAS, on October 4, 2004, plaintiff Service Employees International Union Health and Welfare Fund ("SEIU"), in its individual capacity and on behalf of a putative class, sued Abbott in the District Court under the caption *SEIU v. Abbott Laboratories*, No. 04-cv-4203 (the "SEIU Action"); and

WHEREAS, on May 2, 2005, the District Court consolidated the Doe Action and the SEIU Action under the caption *In re Abbott Laboratories Norvir Antitrust Litigation*, No. C 04-1511 (the "Action"); and

WHEREAS, on June 11, 2007, the District Court granted, in part, the motion of Individual Plaintiffs and SEIU (together, "Plaintiffs") for class certification, and certified a nationwide Class (defined below) for injunctive relief under federal antitrust law and for equitable relief under California Business & Professions Code §§ 17200, *et seq.* and the unjust enrichment laws of 48 states; and

WHEREAS, on May 16, 2008, the District Court, inter alia, granted Abbott's Motion for Summary Judgment dismissing Plaintiffs' restitution claims based on the unjust enrichment laws of 48 states; and

WHEREAS, on June 11, 2007, the District Court appointed Doe and SEIU as the Class Representatives (defined below), but held that Doe 2 could not serve as a Class Representative; and

WHEREAS, the District Court also created two subclasses, appointing Doe as the Class Representative for a subclass of individual Class Members comprised of consumers of Norvir (the "Individual Class Members") and SEIU as the Class Representative for a subclass of institutional Class Members comprised of third-party payors who paid in whole or in part for Norvir (the "Institutional Class Members," together with the Individual Class Members, the "Class Members"); and

WHEREAS, on March 14, 2008, the District Court approved a plan for providing notice to the Class and, pursuant to that plan, Class Members were notified of the Action and the certification thereof as a class action, and allowed Class Members until June 15, 2008 to request exclusion from the Class;

WHEREAS, the Class Representatives and Class Counsel (defined below) believe that all of Plaintiffs' claims are meritorious, but they have concluded that, in light of the costs, risks, and delay of litigation and likely post-trial appeal of the matters in dispute, particularly in complex class action proceedings, and in light of the desire to provide a benefit to Class Members sooner rather than later, this Settlement Agreement is fair, reasonable, adequate, and in the best interests of the Class; and

WHEREAS, Abbott denies any liability and asserts various defenses to liability that it believes are meritorious, but it has concluded that, in light of the costs, disruption, and risks of litigation, that this Settlement Agreement is fair, reasonable, and in its best interests;

NOW THEREFORE, without any admission or concession whatsoever on the part of the Class Representatives of any lack of merit in the Action, and of all of the claims asserted therein, and without any admission or concession whatsoever of any liability or wrongdoing or lack of merit in its defenses by Abbott, it is hereby stipulated and agreed that, in consideration of the agreements, promises and covenants set forth in this Settlement Agreement, which is subject to the approval of the District Court pursuant to Rule 23 of the Federal Rules of Civil Procedure and the other conditions set forth in this Settlement Agreement, the Action shall be fully and finally settled under the following terms and conditions:

ADDITIONAL DEFINITIONS

- 1. As used in this Settlement Agreement and the related documents attached hereto as Exhibits, the following terms shall have the meanings set forth below:
- a. "Class Counsel" or "Co-Lead Counsel" means Berman, DeValerio, Pease, Tabacco, Burt & Pucillo and Labaton Sucharow LLP.

b. "Class" means:

All persons or entities throughout the United States and its territories who purchased or paid for, or who reimbursed another person or entity who purchased or paid for, Norvir as a booster to other protease inhibitors intended for consumption by themselves, their families, or their members, employees, plan participants and beneficiaries or insureds, and who paid all or part of the cost of Norvir during the period December 3, 2003 through July 30, 2008 ("Settlement Class Period"). Excluded from the Class are: (1) persons or entities that excluded themselves from the Class; (2) Abbott and its subsidiaries and affiliates; (3) all government entities (except for government-funded employee benefit funds); and (4) all persons or entities that purchased Norvir: (i) for purposes of resale, or (ii) directly from Abbott.

- c. "Class Notice" means the notice of the terms of this Settlement Agreement to be provided to the Class, which the Parties (defined below) shall jointly submit to the District Court for its approval.
- d. "Conditions Precedent" means the events specified in Paragraph 2 of this Settlement Agreement that must occur before the Settlement becomes effective as set forth herein.
- e. "Defendant" or "Abbott" means Abbott and its subsidiaries, parents, affiliates, successors, predecessors, officers, directors, employees, agents, principals, attorneys, successors-in-interest and assigns.
- f. "Defendant's Counsel" or "Abbott's Counsel" means Winston & Strawn LLP and Munger, Tolles & Olson LLP.
- g. "Direct Actions" means the following cases and claims by direct purchasers and competitor alleged in connection with those cases: (a) Meijer, Inc. & Meijer Distribution, Inc. v. Abbott Laboratories, C 07-5985 CW, (b) Rochester Drug Cooperative, Inc. v. Abbott Laboratories, C 07-6010 CW, (c) Louisiana Wholesale Drug Company, Inc. v. Abbott Laboratories, C 07-6118 CW, (d) Safeway Inc., et al. v. Abbott Laboratories, C 07-5470 CW, (e) Rite Aid Corporation, et al. v. Abbott Laboratories, C 07-6120 CW, and (f) Smithkline Beecham Corporation d/b/a/ GlaxoSmithKline v. Abbott Laboratories, C 07-5702 CW, all pending in the District Court.
- h. "Effective Date" means the first day on which all Conditions Precedent have been satisfied.
- i. "Final Approval Hearing" means the hearing at which the District Court shall determine whether to grant final approval of this Settlement Agreement.

- j. "Final Approval Order" means the order, substantially in the form attached as Exhibit A, in which the District Court grants final approval of this Settlement Agreement and authorizes the entry of a final judgment and dismissal of the Action ("Final Approval").
- k. "Final Payment" means the \$17.5 million payment Abbott is obligated to make if Plaintiffs are the Prevailing Party (defined below) on appeal.
- 1. "Initial Payment" means the non-refundable \$10 million payment Abbott is obligated to make if the Ninth Circuit (defined below) grants interlocutory appeal with respect to two or more issues, or the Ninth Circuit grants interlocutory appeal on only one issue and Abbott declines to terminate the Settlement Agreement.
- m. "Net Final Payment" means the Final Payment net of any court-ordered attorneys' fees, costs, and incentive award payments to Plaintiffs.
- n. "Net Initial Payment" means the Initial Payment net of any court-ordered attorneys' fees, costs, and incentive award payments to Plaintiffs.
- o. "Ninth Circuit" means the United States Court of Appeals for the Ninth Circuit.
- p. "Parties" means Doe and SEIU (together, the "Class Representatives"), Defendant and Doe 2.
- q. "Preliminary Approval Order" means the order, substantially in the form attached as Exhibit B, in which the District Court grants preliminary approval to this Settlement Agreement.
- r. "Released Claims" means any claims, demands, actions, causes of action or liability of any nature, whether known or unknown, derivative or direct, suspected or

unsuspected, accrued or unaccrued, asserted or unasserted, whether in law or in equity including, without limitation, claims which have been asserted or could have been asserted in the Action, or any litigation against Abbott arising out of the matters alleged in the Action that any Releasor (defined as any Plaintiff or any Class Members) now has, ever had, could have had or may have had as of the date this Settlement Agreement is executed (whether or not such Releasor objects to the settlement and whether or not he/she or it makes a claim upon or participates in the Settlement Fund, whether directly, representatively, derivatively or in any other capacity), and that all Abbott shall be forever released and discharged from any and all liability in respect of the Released Claims. Notwithstanding the above, no claims alleging damages and/or seeking non-monetary relief caused by the failure of Norvir to be safe and/or effective or alleging other conduct not related to, or arising from, claims of the type alleged or argued in the Action including, without limitation, claims asserted in the Direct Actions, personal injury claims, product defect claims, securities claims, breach of contract claims, breach of warranty claims, negligence claims, tort claims, are Released Claims.

s. "Subclass" means the Individual Class Members and the Institutional Class Members.

CONDITIONS PRECEDENT

- 2. Before this Settlement Agreement becomes effective, each of the following Conditions Precedent must occur, subject to the termination provisions set forth in paragraphs 23 through 28:
 - a. Entry of the Preliminary Approval Order;
 - b. The District Court must enter one or more orders that:

- i) stay all current deadlines in this Action, including the trial date, pending Final Approval;
- ii) certify for interlocutory appeal under 28 U.S.C. § 1292(b) the following three issues (described with an initial paragraph for context) addressed in the District Court's rulings on dispositive motions and related orders in this Action:

In this case, Plaintiffs have alleged that Abbott's pricing decisions in December 2003 violated the Sherman Act under a monopoly-leveraging theory, and California Unfair Competition Law under Business & Professions Code §§ 17200, et seq., and, further, that such conduct unjustly enriched Abbott. Plaintiffs claim that Abbott raised the price of a patented drug (Norvir) by 400% (representing a \$6.84 increase per 100 mg daily dose) in one alleged market (the Booster Market) in an effort to create or maintain a monopoly for another Abbott drug known as Kaletra in a separate alleged market (the Boosted Market). Norvir's active ingredient is called "ritonavir." Kaletra is a co-formulated product that includes both ritonavir and a protease inhibitor known as "lopinavir." The three proposed interlocutory issues are:

<u>Issue One</u>: Whether, as a matter of law, a plaintiff can establish antitrust injury based on the payment of an increased price for a patented product in the leveraging market, where the plaintiff contends the price increase was designed to maintain or create a monopoly in the leveraged market?

<u>Issue Two</u>: Whether, as a matter of law, a plaintiff can potentially establish monopoly power – in a case where the defendant allegedly used exclusionary pricing to slow a market share decline – where some existing competitors have increased both their market share and prices since the challenged pricing decision?

<u>Issue Three</u>: Whether the Ninth Circuit's decision in *Cascade Health Solutions v. Peacehealth*, 515 F.3d 883 (9th Cir. 2008), mandates judgment against a monopoly leveraging claim based on unilateral pricing conduct where there is no allegation of below-cost pricing?

- c. The Ninth Circuit must permit an interlocutory appeal on the merits of at least two issues certified by the District Court, or if only one issue is accepted by the Ninth Circuit, Abbott must not exercise its right to withdraw from the Settlement Agreement; and
 - d. Final Approval.

RIGHTS AND OBLIGATIONS

- 3. Upon execution of this Settlement Agreement, the Parties will file the following documents in the District Court:
- a. A motion for entry of the Preliminary Approval Order and to continue the stay of all current deadlines in this Action pending Final Approval; and
- b. A joint motion requesting certification, under 28 U.S.C. § 1292(b), of an interlocutory appeal, consistent with paragraph 2.b.(ii).

The District Court Proceedings

- 4. If the District Court certifies all three issues for interlocutory appeal, Abbott will file an unopposed petition with the Ninth Circuit for interlocutory appeal.
 - 5. Plaintiffs agree they will:
- a. fully support the petition, subject to a right of qualification where there is language in the petition that (i) operates as an admission by Plaintiffs to their detriment and/or (ii) exceeds the scope of what Plaintiffs have agreed to under the terms of this Settlement Agreement;
- b. agree that the controlling standard for Section 1292(b) appeals is satisfied; and
- c. agree that circumstances of this case warrant the exercise of the Ninth Circuit's discretion to accept the interlocutory appeal for all three issues.
- 6. Plaintiffs also authorize Abbott to represent their agreements as recited above in paragraph 5 to the Ninth Circuit in Abbott's brief seeking an interlocutory appeal.
- 7. Within 5 business days of Abbott's filing its petition in the Ninth Circuit, Plaintiffs will file a responsive brief in the Ninth Circuit that is limited to 5 pages confirming their representations in paragraph 5 and urging the Ninth Circuit to accept the interlocutory

appeal on all issues presented in the petition while making it clear that Plaintiffs reserve their rights to oppose the substance of Abbott's arguments.

8. The Parties will cooperate to make whatever filings are necessary, as expeditiously as possible, including filing a joint appendix, to facilitate the Ninth Circuit's acceptance of the interlocutory appeal.

The Ninth Circuit Proceedings

- 9. If the Ninth Circuit accepts at least two issues for interlocutory appeal (or only one issue and Abbott declines to terminate this Settlement Agreement), Abbott will, within 10 business days of the Ninth Circuit's order granting permission, make the Initial Payment to the Class to be held in an interest bearing account by Citibank, a third-party escrow agent, that will hold the Initial Payment until the appellate process is complete, except as provided in paragraph 29 herein. If the District Court does not enter a Final Approval Order at the Final Approval Hearing, Abbott shall receive its Initial Payment back, minus the Class Notice costs and administration as provided in paragraph 29. This payment otherwise shall be non-refundable as provided herein.
- 10. If the Ninth Circuit does not accept at least two of the proposed issues for interlocutory appeal, Abbott may terminate the Settlement Agreement pursuant to the provisions herein.
- 11. The Parties agree to reasonably cooperate to expedite the interlocutory appeal, including filing a joint motion to expedite the appeal under the following briefing schedule, and voluntarily filing their briefs on this schedule in any event:
- a. Abbott will provide Plaintiffs with a substantially finalized draft of its brief (*i.e.*, it includes in substance every Abbott argument) no later than 15 days prior to filing its brief (which will be held in confidence, which will not waive the work-product privilege, and

will never be quoted in public or to a court); and then file its opening brief no later than 10 days after the appellate record is filed;

- b. Plaintiffs will file their opposition brief within 30 days after receiving Abbott's filed brief; and
- c. Abbott will file its reply brief within 12 days of receiving Plaintiffs' filed opposition brief.
- 12. The Parties agree that absent a mutual agreement in writing, no Party shall request from the Ninth Circuit or the Ninth Circuit's clerk additional time for any filing during the course of the appellate process, whether by motion or otherwise.
- 13. Subject to performance of the Conditions Precedent specified in paragraph 2, the Net Initial Payment will be distributed on a *cy pres* basis equally to the 501(c)(3) nonprofit institutions identified in Exhibit C. Abbott shall have 5 business days from execution of this Settlement Agreement to give its consent, which shall not be unreasonably withheld, to each of the institutions identified in Exhibit C. Neither the dissemination of the Class Notice nor Final Approval is a condition precedent to Abbott's making the Initial Payment pursuant to paragraph 9.
- 14. Abbott agrees that the Initial Payment will not reduce, or otherwise operate as a credit or substitute, toward other charitable giving that Abbott would otherwise have made to the same types of organizations.
- 15. If Abbott is the Prevailing Party on appeal, as described in paragraphs 18 and 20, the Parties agree that Abbott shall be entitled to final judgment in the District Court, with prejudice, on all individual and class-wide claims in the Action. In that circumstance, after all

available appellate rights permitted under this Settlement Agreement have been exhausted, the Parties will jointly move for entry of final approval consistent with this paragraph.

- 16. If Plaintiffs are the Prevailing Party as defined in paragraph 21, or if Abbott is the Partially Prevailing Party as defined in paragraph 19, Abbott will make the Final Payment, or, if Abbott is deemed the Partially-Prevailing Party pursuant to paragraph 19, one-fourth of the Final Payment, to the Class to be held in an interest bearing account by Citibank within 10 business days of the conclusion of all proceedings relating to the Ninth Circuit appeal. The Net Initial Payment and Net Final Payment, the amount of which is governed by ¶ 1 and 18-21, will be allocated as follows: (1) 70% shall be distributed on a *cy pres* basis equally among the institutions listed on Exhibit C; and (2) 30% shall be distributed pursuant to a plan of allocation to Individual Class Members who reside in California and Institutional Class Members who have reimbursed or paid in whole or in part for the cost of Norvir for patients residing in California during the Settlement Class Period, with any remaining unclaimed residue being contributed to back to the *cy pres* portion.
- 17. In return for Abbott's payment of the funds specified above, including any payments made in accordance with paragraphs 9 and 16 above regardless of who is the Prevailing Party Plaintiffs will dismiss their individual and class-wide claims in the Action with prejudice upon the exhaustion of all appellate rights (including, if appropriate, any petition for rehearing and/or petition for writ of certiorari), and the Parties will enter into mutual releases as discussed below upon Final Approval. The District Court will retain jurisdiction to enforce the Settlement, subject to paragraph 47.

PREVAILING PARTY STATUS

- 18. For Abbott to be the "Prevailing Party," the Ninth Circuit must accept the substance of Abbott's position on at least one of the issues accepted by the Ninth Circuit on appeal. The following is further clarification of what will qualify Abbott as the prevailing party:
- a. For Issue One, Abbott shall be deemed the Prevailing Party if the Ninth Circuit holds, in substance, that Plaintiffs cannot establish antitrust injury under the law based on the price increase for Norvir;
- b. For Issue Two, Abbott shall be deemed the Prevailing Party if the Ninth Circuit holds that, under the appropriate legal standard, Plaintiffs cannot establish monopoly power under the circumstances of this case; and
- c. For Issue Three, Abbott shall be deemed the Prevailing Party if the Ninth Circuit holds that a showing of below-cost pricing is necessary for the type of Sherman Act claims alleged in the Action.
- 19. Abbott shall be deemed to be the "Partially-Prevailing Party" if, without reaching a decision on the merits of any of the issues it has accepted for appeal falling within paragraph 18 (a), (b), or (c) above, the Ninth Circuit reverses or vacates any challenged ruling or order by the District Court and remands any matter or issue to the District Court for reconsideration or further review based upon a legal or factual standard enunciated by the Ninth Circuit that differs from any standard applied by the District Court. In this circumstance, Abbott will pay one-fourth of the Final Payment to be distributed in accordance with paragraph 16.
- 20. Abbott reserves the right to seek panel rehearing and/or rehearing *en banc* of any adverse ruling by the Ninth Circuit. A determination of Prevailing Party status is contingent upon the final decision from the Ninth Circuit, including, if any, a rehearing decision. The question of whether Abbott is the Prevailing Party under paragraph 18 or a Partially-Prevailing

Party under paragraph 19 turns solely on the final decision of the Ninth Circuit after the appellate process is complete. Nothing in this Agreement shall be construed to preclude Abbott from seeking a writ of certiorari in the United States Supreme Court from the final decision of the Ninth Circuit.

21. To the extent Abbott is not a Prevailing Party or a Partially-Prevailing Party under paragraphs 18 through 20, then Plaintiffs shall be deemed the Prevailing Party.

COURT APPROVAL OF SETTLEMENT

- 22. The Parties shall use their respective best efforts to obtain District Court approval of this Settlement Agreement. The process for obtaining District Court approval of this Settlement Agreement shall be as follows:
- a. <u>Preliminary Approval</u>. By August 13, 2008, or such other date as ordered by the District Court, Class Counsel and Defendant's Counsel shall jointly apply for entry of the Preliminary Approval Order.
- b. <u>Final Approval Hearing.</u> Class Counsel and Defendant's Counsel shall jointly request that the District Court, on a date approved by the Court, which shall be approximately 45 days after the estimated completion of the dissemination of Class Notice, conduct a Final Approval Hearing to determine whether to grant final approval to this Settlement Agreement. At the Final Approval Hearing, the Parties shall seek Final Approval. If the District Court grants Final Approval, then the Parties shall jointly request the District Court to enter a Final Approval Order.

TERMINATION OF AGREEMENT

23. Except as otherwise provided in this Settlement Agreement, and subject to Paragraphs 9 and 13 with regard to the Initial Payment, this Settlement Agreement will

automatically terminate without penalty to any Party if either (a) the District Court declines to enter the Preliminary Approval Order or Final Approval Order; or (b) the Final Approval is reversed by an appellate court ruling.

- 24. The Settlement Agreement will also automatically terminate without penalty to any Party if either the District Court or the Ninth Circuit rejects all issues for interlocutory appeal.
- 25. Abbott, at its election, may terminate this Settlement Agreement without penalty to any Party if:
- a. the District Court does not stay all proceedings in this Action pending Final Approval;
- b. the District Court does not certify all three issues identified in paragraph2.b.2. for interlocutory appeal under 28 U.S.C. § 1292(b);
- c. either the District Court or the Ninth Circuit materially modifies one or more of the three proposed issues for interlocutory appeal;
- d. the Ninth Circuit accepts only one of the three proposed issues for interlocutory appeal; or
- e. the District Court orders that the Class Notice provides an opportunity for Class Members to opt out of the Settlement and if a specified number of Class Members, set forth in a separate letter agreement between Co-Lead Counsel and counsel for Abbott, choose to opt out of the Settlement. The separate letter agreement shall be maintained as Highly Confidential under the Protective Order and will not be filed with the District Court unless ordered by the District Court.

- 26. Except otherwise provided in paragraph 25(e), Abbott must exercise any right to terminate this Settlement Agreement within 7 business days of the date of the relevant court order by sending written notice to the other Parties pursuant to paragraph 31 exercising this right of termination.
- 27. If Abbott elects to terminate within seven (7) business days under the circumstances set forth in paragraph 25 subsections (c)-(d), after the Ninth Circuit accepts the interlocutory appeal, the parties agree to cooperate to voluntarily dismiss the appeal and Abbott will not have the obligation to make any payments under the Settlement Agreement.
- 28. If this Settlement Agreement is terminated for any reason, then, except as otherwise expressly provided: (a) this Settlement Agreement shall be rendered null and void; (b) this Settlement Agreement and all negotiations and proceedings relating hereto shall be of no force or effect, and without prejudice to the rights of the Parties; (c) all Parties shall be deemed to have reverted to their respective status in the Action as of the date and time immediately preceding the execution of this Settlement Agreement and the Parties shall stand in the same position and shall proceed in all respects as if this Settlement Agreement and any related orders had never been executed, entered into, or filed, except that the Parties shall not seek to recover any fees, costs or expenses incurred in connection with this Settlement (except as provided in paragraph 29); and (d) the Parties agree that they will cooperate in promptly making a joint request to the District Court to have trial reset on the next available trial date convenient to the District Court, on the basis of the pretrial proceedings that have already occurred.

CLASS NOTICE AND ADMINISTRATION OF THE SETTLEMENT

29. If the Ninth Circuit accepts at least two issues on appeal (or if the Ninth Circuit accepts one issue and/or modifies one or more issues and Abbott does not exercise its right to

terminate the Settlement Agreement) the Parties shall in good faith cooperate with each other to draft a mutually agreeable Class Notice and shall provide the Court with a proposed plan of notice to the Class of the Settlement Agreement. Class Notice and administration of this proposed Settlement will be given as approved by the District Court, shall be paid for out of the Initial Payment and shall be non-refundable.

30. The Parties shall select, subject to District Court approval, an independent thirdparty administrator to arrange for publication and other distribution of Class Notice, to
administer any payments required under this Settlement Agreement, to maintain a website
containing pertinent documents and to respond to Class Member inquiries. Class Counsel will
have the right to oversee and monitor the settlement administrator and the settlement
administration. The settlement administrator shall be subject to the authority and continuing
jurisdiction of the District Court.

NOTICES

31. All notices that any Party to this Settlement Agreement may be required or may wish to give in connection with this Settlement Agreement may be given by the Party desiring to give such notice or notices by addressing them to the other Parties at the addresses set forth below (or at such other addresses as may be designated by written notices given in the manner designated herein). Notice by email shall be sufficient. The addresses of the Parties until further notice are:

For: Abbott

James F. Hurst, Esq. WINSTON & STRAWN LLP 35 W. Wacker Drive Chicago, Illinois 60601 jhurst@winston.com For: Plaintiffs

Joseph J. Tabacco, Jr., Esq.
BERMAN DEVALERIO PEASE
TABACCO BURT & PUCILLO
425 California Street, Suite 2100
San Francisco, CA 94104-2205
jtabacco@bermanesq.com

Hollis Salzman, Esq. LABATON SUCHAROW LLP 140 Broadway New York, NY 10005 hsalzman@labaton.com

ATTORNEYS' FEES AND COSTS

- 32. Class Counsel may petition the District Court for an award of attorneys' fees, costs and incentive awards to plaintiffs (the "Fee Petition") from the Initial Payment, or, at their option, Class Counsel may defer filing a Fee Petition until after the Action has been concluded, or bring a second Fee Petition. Depending on the outcome of the interlocutory appeal contemplated by this Settlement Agreement, Class Counsel may also file a Fee Petition with respect to the Final Payment as a consequence of Plaintiffs either being deemed the Prevailing Party or Abbott being deemed to be a Partially-Prevailing Party. Abbott will take no position on either or both of those petitions.
- 33. In no event shall Abbott be responsible for the direct payment of attorneys' fees or costs, including costs associated with the administration of the Settlement beyond what is contemplated to be paid under this Settlement Agreement. Any payment of attorneys' fees, costs, and incentive awards including costs associated with the administration of the Settlement and the provision of Notice to the Class, shall be made from the Initial Payment and/or the Final Payment as requested by Class Counsel and approved by the District Court.

34. The Parties agree that the rulings of the District Court regarding the amount of attorneys' fees, costs, and incentive awards will be separate from the remaining matters to be considered by the District Court at the Final Approval Hearing as provided for in this Settlement Agreement. If the District Court approves the fairness of the Settlement, then the Settlement will become final regardless of any subsequent appeal directed solely to the ruling of the District Court pertaining to a Fee Petition.

RELEASES

- 35. Upon the occurrence of the Effective Date the Releasors shall be deemed to have covenanted and agreed, and each Plaintiffs' Counsel, as agent for its respective Class Representative, hereby covenants and agrees and the Final Approval Order provide that each Releasor hereby is forever barred from instituting, assigning, maintaining, collecting or prosecuting against Abbott any and all Released Claims.
- 36. With respect to the above releases and all Released Claims, the Parties and Class Members shall be deemed to have, and by operation of this Settlement Agreement shall have, waived any and all provisions, rights and benefits conferred by any law of any state or territory of the United States, or principle of common law, which is similar, comparable, or equivalent to Cal. Civ. Code § 1542, which provides:

A general release does not extend to claims which the creditor does not know or suspect to exist in his or her favor at the time of executing the release, which if known by him or her must have materially affected his or her settlement with the debtor.

SETTLEMENT AGREEMENT RESTRICTIONS

37. Neither the acceptance by Abbott of the terms of the Settlement Agreement nor any of the related negotiations or proceedings is or shall be argued, construed as or deemed to be

evidence of any violation of any statute or law or an admission of any liability or wrongdoing or damages by Abbott, or of the merits of the claims alleged in the Action. Abbott expressly denies legal liability or any wrongdoing of any sort toward Plaintiffs and Class Members.

38. This Settlement Agreement and related documents shall not be used, offered or received into evidence in the Action for any purpose other than to enforce, construe or finalize the terms of the Settlement Agreement and/or to obtain the Preliminary and Final Approval by the District Court of the terms of the Settlement Agreement.

MUTUAL NON-DISPARAGMENT

39. As part of this Settlement Agreement, Doe in his individual capacity and on behalf of the Individual Class Members he represents, John Doe 2 individually, and SEIU in its individual capacity and on behalf of the Institutional Class Members, along with Class Counsel, agree individually and collectively that they will not disparage in any way Abbott or its products (including but not limited to its patented drugs) and will refrain from any tortious interference with Abbott's contracts, relationships and prospective economic advantage. Likewise, Abbott, along with Abbott's Counsel, will not disparage in any way Plaintiffs, individually or collectively, and will refrain from any tortious interference with their contracts, relationships and prospective economic advantage.

MISCELLANEOUS PROVISIONS

40. <u>No Assignment</u>. Each Party represents, covenants and warrants that he, she or it has not directly or indirectly assigned, transferred, encumbered or purported to assign, transfer, or encumber to any person or entity any portion of any liability, claim, demand, cause of action or rights that he or she releases in this Settlement Agreement.

- 41. <u>Binding On Assigns</u>. This Settlement Agreement shall be binding upon and inure to the benefit of the Parties and their respective heirs, trustees, executors, successors and assigns.
- 42. <u>Construction</u>. The Parties agree that the terms and conditions of this Settlement Agreement are the result of lengthy, intensive arm's-length negotiations between the Parties and that this Settlement Agreement shall not be construed in favor or against any Party by reason of the extent to which any Party, or his, her or its counsel, participated in the drafting of this Settlement Agreement.
- 43. <u>Counterparts</u>. This Settlement Agreement, and any amendments hereto, may be executed in any number of counterparts, and any Party may execute any such counterpart, each of which when executed and delivered shall be deemed to be an original and all of which counterparts taken together shall constitute but one and the same instrument.
- 44. <u>Governing Law</u>. Construction and interpretation of the Settlement Agreement shall be determined in accordance with the laws of the State of California.
- 45. <u>Integration Clause</u>. This Settlement Agreement, including the referenced Exhibits, which form an integral part of this Settlement Agreement, contains the entire understanding of the Parties in respect of the subject matter of this Settlement Agreement. This Agreement may not be changed, altered or modified, except in a writing signed by the Parties.
- 46. <u>Incorporation of Exhibits</u>. All Exhibits are incorporated into this Settlement Agreement by reference. Any inconsistency between the Settlement Agreement and the Exhibits attached to this Settlement Agreement shall be resolved in favor of this Settlement Agreement.
- 47. <u>Dispute Resolution</u>. To the extent permitted by law, all disputes arising under or relating to this Settlement Agreement, including whether Abbott or Plaintiffs are the Prevailing Party, shall be resolved by binding arbitration through Judicial Arbitration Mediation

Services (JAMS) by one of three arbitrators selected by the Honorable Edward A. Infante (Ret.). Upon receiving a list of three potential mediators from Judge Infante, the Parties will seek to reach an agreement on one arbitrator. Absent an agreement, they will each have the opportunity to strike one arbitrator with the remaining arbitrator to decide any issue. Judge Infante will resolve any disputes about this procedure. If Plaintiffs initiate the arbitration, the Parties will evenly split the cost and fees of the arbitrator. If Abbott initiates the arbitration, Abbott will be solely responsible for the costs and fees of the arbitrator.

- 48. <u>Parties' Authority</u>. The signatories to this Settlement Agreement represent that they are fully authorized to enter into this Agreement and bind the Parties to the terms and conditions hereof.
- 49. <u>Receipt Of Advice Of Counsel</u>. The Parties acknowledge, agree, and specifically warrant to each other that they have read this Settlement Agreement, have received legal advice with respect to the advisability of entering into this Settlement, and fully understand its legal effect.
- 50. Agreement To Cooperate. All Counsel and the Parties agree to cooperate fully with one another in seeking the Preliminary Approval Order and to promptly agree upon and execute all such other documentation as may be reasonably required to obtain final approval by the District Court of the Settlement.

IN WITNESS WHEREOF, the undersigned counsel, on behalf of their respective clients, have executed this Settlement Agreement, intending to be legally bound hereby if each of the conditions precedent occur or as otherwise stated herein:

ABBOTT LABORATORIES INC.

By:

James F. Hurst

WINSTON & STRAWN LLP

35 W. Wacker Drive Chicago, Illinois 60601

Date:

8-13-08

JOHN DOE 1 and JOHN DOE 2, on behalf of themselves and others similarly situated

By:

Joseph J. Tabacco, Jr.

BERMAN DEVALERIO PEASE TABACCO BURT & PUCILLO 425 California Street, Suite 2100

San Francisco, CA 94104-2205

Date:

8-17-08

SERVICE EMPLOYEES
INTERNATIONAL UNION HEALTH
AND WELFARE FUND, on behalf of itself
and others similarly situated

By:

Hellis Salzman /

Hollis Salzman

LABATON SUCHAROW LLP

140 Broadway

New York, NY 10005

Date: 🖇

8-13-08

EXHIBIT A

| 1 2 3 4 5 | Joseph J. Tabacco, Jr. (75484) Christopher T. Heffelfinger (118058) James C. Magid (233043) BERMAN DEVALERIO PEASE TABACCO BURT & PUCILLO 425 California Street, Suite 2100 San Francisco, CA 94104 Telephone: (415) 433-3200 Facsimile: (415) 433-6382 | |
|--------------------------|--|---|
| 6 | Co-Lead Class Counsel for Plaintiff John Doe and Individual Class Members, Counsel for Plaintiff John Doe 2 | 1 |
| 8 9 10 11 12 | Hollis Salzman (HS-5994) Michael W. Stocker (179083) Kellie Safar Lerner (KL-0927) LABATON SUCHAROW LLP 140 Broadway New York, NY 10005 Telephone: (212) 907-0700 Facsimile: (212) 818-0477 Co-Lead Class Counsel for Plaintiff Service Electronational Union Health and Welfare Fund | |
| 13 | International Union Health and Welfare Fund and Institutional Class Members | |
| 14 | UNITED STATES DISTRICT COURT | |
| 15 | NORTHERN DISTR | ICT OF CALIFORNIA |
| 16 | OAKLAN | D DIVISION |
| 17 | | |
| 18 | IN RE ABBOTT LABORATORIES NORVIR () ANTITRUST LITIGATION | Case No. C-04-1511 CW |
| 19 | ANTITRUST LITIGATION | [PROPOSED] ORDER GRANTING MOTION FOR PRELIMINARY |
| 20 | | APPROVAL OF CLASS ACTION SETTLEMENT |
| 21 | | |
| 22 | | Date: August 19, 2008 Time: 2:00 p.m. |
| 23 | | Ctrm: 2, The Honorable Judge Wilken |
| 24 | | |
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| | [C-04-1511 CW] [PROPOSED] ORDER GRAN' APPROVAL OF CLASS ACTION SETTLEMEN | |

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[C-04-1511 CW] [PROPOSED] ORDER GRANTING MOTION FOR PRELIMINARY APPROVAL OF CLASS ACTION SETTLEMENT

Upon consideration of Plaintiffs' Motion for Preliminary Approval of Proposed Settlement with Abbott Laboratories, Inc. ("Abbott"), it is hereby **ORDERED** as follows:

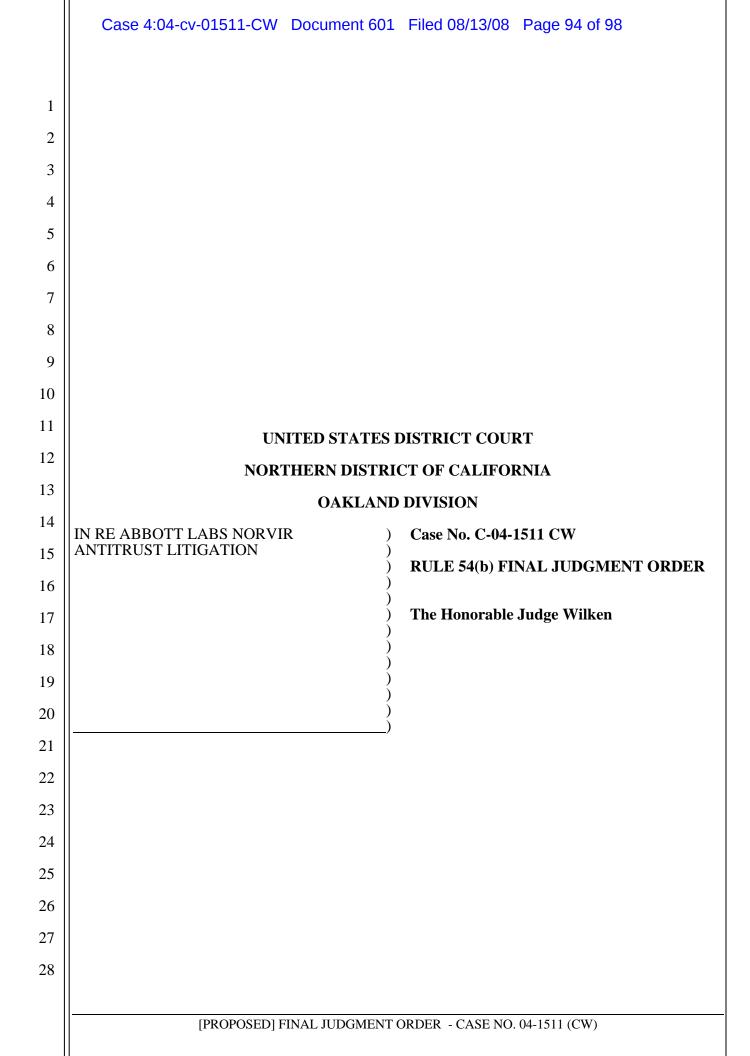
- 1. The Motion is hereby **GRANTED**.
- The Court finds that the proposed Settlement with Abbott, as set forth in the 2. Settlement Agreement, and subject to a final determination following a hearing after notice to the Class ("Class Notice"), is sufficiently fair, just, equitable, and in the best interests of the members of the Class.
- 3. The modification of the Class definition proposed by the parties is hereby **APPROVED.** The Class is now defined as the following:

All persons or entities throughout the United States and its territories who purchased or paid for, or who reimbursed another person or entity who purchased or paid for, Norvir as a booster to other protease inhibitors intended for consumption by themselves, their families, or their members, employees, plan participants and beneficiaries or insureds, and who paid all or part of the cost of Norvir during the period December 3, 2003 through July 30, 2008 ("Settlement Class Period"). Excluded from the Class are: (1) persons or entities that excluded themselves from the Class; (2) Abbott and its subsidiaries and affiliates; (3) all government entities (except for government-funded employee benefit funds); and (4) all persons or entities that purchased Norvir: (i) for purposes of resale, or (ii) directly from Abbott.

- 4. Pending the Court's further review of the Settlement Agreement, all proceedings in the Action, other than proceedings pursuant to the Settlement, shall be stayed pending the hearing, pursuant to Rule 23(e) of the Federal Rules of Civil Procedure, to determine the fairness, reasonableness, and adequacy of the proposed Settlement and whether it should be finally approved ("Final Approval Hearing"), and all Class Members shall be enjoined from commencing any other action based upon any of the claims at issue in the above-captioned action (the "Action").
- 5. If and when the Ninth Circuit accepts the interlocutory appeal proposed in the parties' Joint Motion To Certify Issues For Interlocutory Appeal Pursuant To 28 U.S.C. § 1292(b) and Abbott does not terminate the Settlement Agreement under the terms of the Settlement Agreement, the parties shall jointly request (a) a date by which they will file a motion for approval of Class Notice and Plan of Notice to the Class; (b) a schedule for Class Members to exclude themselves from the Class; (c) a schedule for the submission of briefing by any Class Member who seeks to object to the Settlement; and (d) a schedule for Final Approval of the Settlement. Plaintiffs will also

1 move the Court for a schedule to submit an application for attorneys' fees, costs and incentive 2 awards. 6. 3 Jurisdiction is hereby retained over this Action and the parties to the Action, and each 4 of the Class Members for all matters relating to this Action, the Settlement, including (without 5 limitation) all matters relating to the administration, interpretation, effectuation, and/or enforcement 6 of the Settlement and this Order, other than as set forth by the Settlement Agreement. 7 7. If the Court does not grant final approval of the Settlement, the Settlement shall be 8 deemed null and void and shall have no further force and effect, and neither the Settlement nor the 9 negotiations leading to it shall be used or referred to by any person or entity in this or in any other 10 action or proceeding for any purpose. The parties shall then promptly move the Court to reset the 11 date for trial on the next available date convenient to the Court on the basis of the pretrial 12 proceedings that have already occurred. In such event, any order entered by this Court in accordance 13 with the terms of the Settlement shall be treated as vacated, *nunc pro tunc*. 14 Dated: 15 CLAUDIA WILKEN 16 UNITED STATES DISTRICT JUDGE 17 18 19 20 21 22 23 24 25 26 27 28

EXHIBIT B



| 1 | The Court has considered Plaintiffs' Motion for Final Approval of Class Action Settlemen | |
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| 2 | with defendant Abbott Laboratories, Inc. ("Abbott") and has held a duly-noticed final approva | |
| 3 | hearing on, 2008. The Court expressly directs the entry of Final Judgment: | |
| 4 | It is hereby ORDERED , ADJUDGED AND DECREED as follows: | |
| 5 | 1. This Final Approval Order incorporates by reference the definitions in the Settlement | |
| 6 | Agreement. | |
| 7 | 2. The Court has jurisdiction over the subject matter of the Action and over all parties to | |
| 8 | the Action, including all Class Members and Subclass Members, as certified by the Court's June 11, | |
| 9 | 2007 order and as modified by the Court's, 2008 Preliminary Approval Order. | |
| 10 | 3. The Court finds that the Settlement was based on vigorous arm's length negotiations | |
| 11 | which were undertaken in good faith by counsel with significant experience litigating antitrust class | |
| 12 | actions. | |
| 13 | 4. The Court finds that the Settlement Agreement with Abbott is fair, reasonable and | |
| 14 | adequate to the Class within the meaning of Rule 23 of the Federal Rules of Civil Procedure. | |
| 15 | 5. The Settlement Agreement, filed concurrently with the preliminary approval motion, | |
| 16 | is finally approved. | |
| 17 | 6. The Court retains jurisdiction to, among other things, implement and enforce the | |
| 18 | Settlement Agreement, subject to dispute resolution provisions in Paragraph 47 of the Settlement | |
| 19 | Agreement. The Court will enter judgment in this case and any additional orders required by the | |
| 20 | Settlement Agreement, including order(s) with respect to any Fee Petition(s) filed by Plaintiffs' | |
| 21 | Counsel, once the Ninth Circuit resolves the interlocutory appeal in this Action. | |
| 22 | DONE AND ORDERED in Chambers in Oakland, California thisday of | |
| 23 | , 2008. | |
| 24 | | |
| 25 | CLAUDIA WILKEN | |
| 26 | CLAUDIA WILKEN UNITED STATES DISTRICT JUDGE | |
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EXHIBIT C

EXHIBIT C

PROPOSED LIST OF CY PRES RECIPIENTS

AIDS Action Foundation, DC (www.aidsaction.org). The AIDS Action Foundation is the 501(c)(3) research and education arm of AIDS Action, and conducts federal HIV policy analysis, research and training, as well as leadership development experiences for young adults through the Pedro Zamora Public Policy Fellowship program. The Foundation develops and disseminates educational materials on the latest public policies and programs, the demographic impact of HIV, and medical research.

AIDS Foundation of Chicago (www.aidschicago.org). The AIDS Foundation of Chicago is a 501(c)(3) public charity that provides funding to and coordinates the activities of local AIDS service providing agencies and engages in public education and policy analysis.

AIDS Resource Center of Wisconsin (www.arcw.org). The AIDS Resource Center of Wisconsin provides a vast array of health and social services to over 3,000 Wisconsin residents living with HIV. Through a wide variety of aggressive AIDS prevention programs, it makes over 150,000 prevention contacts every year with people who are at risk for contracting HIV.

Atlanta AIDS Partnership Fund (www.aidsfundatlanta.org). The AIDS Fund invests in the strongest HIV prevention, support, residential, and advocacy programs. Since its inception over one decade ago, the AIDS Fund has awarded more than \$9.5 million in grants to help care for people living with HIV/AIDS and to fight the spread of the disease.

Bienestar Human Services Inc. (www.bienestar.org). Bienstar is committed to enhancing the health and well-being of the Latino community and other underserved communities. Bienestar accomplishes this through community education, prevention, mobilization, advocacy, and the provision of direct social support services.

Black AIDS Institute (www.blackaids.org). The Black AIDS Institute is the first Black HIV/AIDS policy center dedicated to reducing HIV/AIDS health disparities by mobilizing Black institutions and individuals in efforts to confront the epidemic in their communities. It is a non-profit, 501(c)(3) charitable organization based in Los Angeles, California.

Brownsville Multi-Service Family Health Center (www.bmsfhc.org). The Brownsville Community Development Corporation offers a wide variety of services to the residents of Brownsville, New York and surrounding neighborhoods. It provides for and seeks to inspire the cultural, economic, medical, and educational well-being of every individual and family in its communities. Among the services it provides is the Brownsville Community Awareness Program - which consists of six highly integrated

HIV and AIDS services, including the award-winning Community Follow-up Program and Positive Options.

Latino Commission on AIDS (www.latinoaids.org). The Latino Commission on AIDS is a nonprofit membership organization dedicated to fighting the spread of HIV/AIDS in the Latino community. The Commission realizes its mission by spearheading health advocacy for Latinos, promoting HIV education, developing model prevention programs for high-risk communities, and by building capacity in community organizations. Since 1995, the Commission has steadily expanded its services outside New York to meet the emerging needs of Latino communities in more than 40 States and Puerto Rico.

New Orleans AIDS Task Force (www.noaidstaskforce.org). The New Orleans AIDS Task Force works to reduce the spread of HIV infection, provide services, advocate empowerment, safeguard the rights and dignity of HIV-affected individuals, and provide for an enlightened public. In the past year, it has answered 1,455 hotline calls, held 3,024 HIV test sessions, and prepared and delivered over 37,795 meals.

South Florida AIDS Network (www.jhsmiami.org). The South Florida AIDS Network was the first organization in Miami-Dade County to provide client advocacy/case management and related support services to people with HIV/AIDS. SFAN is now the single largest comprehensive HIV/AIDS service provider in Miami-Dade County.

UCSF AIDS Health Project (www.ucsf-ahp.org). The UCSF AIDS Health Project is a program of the University of California San Francisco's Department of Psychiatry and San Francisco General Hospital – both ranked among the best HIV programs in the United States. It has championed HIV emotional and psychological support services since 1984.

UCSF Center for AIDS Prevention Studies (www.caps.ucsf.edu). The mission of the Center for AIDS Prevention Studies is to conduct domestic and international research to prevent the acquisition of HIV and to optimize health outcomes among HIV-infected individuals.

Whitman Walker Clinic (www.wwc.org). The Whitman-Walker Clinic is a non-profit community-based health organization serving the Washington, DC metropolitan region. Established by and for the gay and lesbian community, the Clinic is comprised of diverse volunteers and staff who provide or facilitate the delivery of high quality, comprehensive, accessible health care and community services. Whitman-Walker Clinic is especially committed to ending the suffering of all those infected and affected by HIV/AIDS.